

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

**AMENDMENT NO. 1
to
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

Nuwellis, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	3845 (Primary Standard Industrial Classification Code Number)	68-0533453 (I.R.S. Employer Identification Number)
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**12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200**

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

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

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

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

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

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

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

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

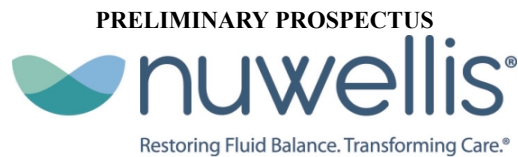
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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



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

SUBJECT TO COMPLETION, DATED JANUARY 30, 2024



NUWELLIS, INC.

**Up to 16,326,530 Units consisting of
16,326,530 Shares of Common Stock and
16,326,530 Common Warrants to purchase up to 16,326,530 Shares of Common Stock
Up to 16,326,530 Shares of Common Stock Underlying the Common Warrants included in the Units**

**Up to 16,326,530 Pre-Funded Units consisting of
16,326,530 Pre-Funded Warrants to purchase up to 16,326,530 Shares of Common Stock and
16,326,530 Common Warrants to purchase up to 16,326,530 Shares of Common Stock**

**Up to 16,326,530 Shares of Common Stock Underlying the Pre-Funded Warrants included in the Pre-Funded Units
Up to 16,326,530 Shares of Common Stock Underlying the Common Warrants included in the Pre-Funded Units**

We are offering on a reasonable best efforts basis up to 16,326,530 units, each unit consisting of one share of common stock and one common warrant to purchase one share of common stock, at an assumed offering price of \$0.49 per unit, which is equal to the closing price of our common stock on the Nasdaq Capital Market on January 26, 2024 for gross proceeds of up to \$8,000,000. The common warrants included in the units will have an exercise price of \$0.49 per share (equal to 100% of the public offering price of each unit sold in this offering), will be exercisable immediately and will expire five (5) years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon the exercise of the common warrants included in the units.

We are also offering to certain purchasers whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and the same common warrant described above with each share of common stock, in lieu of units that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. The purchase price of each pre-funded unit will be equal to the price per unit being sold to the public in this offering, minus \$0.0001, and the exercise price of each pre-funded warrant included in the pre-funded units will be \$0.0001 per share. The pre-funded warrants will be exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. For each pre-funded unit we sell, the number of units (and shares of common stock) we are offering will be decreased on a one-for-one basis. This offering also relates to the shares of common stock issuable upon the exercise of the pre-funded warrants and the common warrants included in the pre-funded units.

The shares of common stock or pre-funded warrants, as the case may be, and the common warrants included in the units or the pre-funded units, can only be purchased together in this offering, but the securities contained in the units or pre-funded units will be issued separately and will be immediately separable upon issuance.

The securities will be offered at a fixed price and are expected to be issued in a single closing. We expect that the offering will end two trading days after it is priced, unless completed sooner or unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date; however, notwithstanding the foregoing, the shares of our common stock underlying the pre-funded warrants and the common warrants will be offered on a continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended. We expect the offering of units and pre-funded units to be completed not later than two business days following the commencement of sales of such securities (after the effective date of the registration statement of which this prospectus forms a part) and we will deliver all such securities to be issued in connection with this offering delivery versus payment or receipt versus payment, as the case may be, upon receipt of investor funds received by us. Accordingly, neither we nor the placement agents have made any arrangements to place investor funds in an escrow account or trust account since the placement agents will not receive investor funds in connection with the sale of the securities offered hereunder.

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

Our common stock is listed on the Nasdaq Capital Market under the symbol "NUWE." On January 26, 2024, the closing price of our common stock on the Nasdaq Capital Market was \$0.49 per share. The actual public offering price per unit or pre-funded unit, as the case may be, will be determined through negotiation among us, the placement agents and the investors in the offering based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final offering price. There is no established trading market for the pre-funded warrants or the common warrants, and we do not expect a market to develop. We do not intend to apply for a listing of the units, the pre-funded units, the pre-funded warrants, or the common warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and the common warrants will be limited.

	Per Unit	Per Pre-Funded Unit	Total
Public offering price	\$	\$	\$
Placement agent fees ⁽¹⁾	\$	\$	\$
Proceeds to us (before expenses)	\$	\$	\$

- (1) We have agreed to pay the placement agents a cash fee equal to 8.0% of the aggregate gross proceeds raised in this offering, and to reimburse the placement agents for certain of their offering-related expenses. See "Plan of Distribution (Conflicts of Interest)" for a description of the compensation to be received by the placement agents.

Lake Street, a placement agent in this offering, has a "conflict of interest" under Rule 5121 of the Financial Industry Regulatory Authority, Inc. ("FINRA") because one of our directors is the head of Life Science Investment Banking and a Managing Director of Lake Street. Accordingly, Maxim has agreed to act as a "qualified independent underwriter" within the meaning of FINRA Rule 5121 in connection with this offering. In its role as a qualified independent underwriter, Maxim has participated in the preparation of this registration statement and the prospectus and has exercised the usual standards of due diligence with respect thereto. For a more complete discussion of the role and compensation of the placement agents, please see the section of this prospectus entitled "Plan of Distribution (Conflicts of Interest)."

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

INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD REVIEW CAREFULLY THE RISKS AND UNCERTAINTIES DESCRIBED HEREIN UNDER THE HEADING "RISK FACTORS" BEGINNING ON PAGE 17 OF THIS PROSPECTUS AND UNDER SIMILAR HEADINGS IN THE OTHER DOCUMENTS THAT ARE INCLUDED IN THIS PROSPECTUS.

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



Restoring Fluid Balance. Transforming Care.®

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (“SEC”). It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with regard to us and the securities being offered hereby. You should review the information and exhibits in the registration statement for further information about us and the securities being offered hereby. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to the filings. You should review the complete document to evaluate these statements.

You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or securities are sold on a later date. Our business, financial condition, results of operations and prospects may have changed since those dates.

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

For investors outside of the United States. We have not, and the placement agents 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 this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

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

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus carefully, including our financial statements and related notes incorporated herein by reference, the information in the section “Risk Factors” and “Where You Can Find Additional Information.” Unless the context otherwise requires, references in this prospectus to the “Company,” “NUWE,” the “registrant,” “we,” “us” and “our” refer to Nuwellis, Inc.

Company Overview

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

Fluid Overload

Fluid overload, also known as hypervolemia, is a condition in which there is too much fluid in the blood, vital organs, and interstitial space, 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, possible signs and symptoms of fluid overload include pulmonary edema/pleural effusion, peripheral edema, anasarca (swelling of the skin) ascites, jugular vein distention and dyspnea.² Medical conditions or diseases where excess fluid accumulates in the body are heart failure, kidney failure, nephrotic syndrome, cirrhosis, or burn injuries/trauma. Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery, although fluid overload is the leading cause of death for critically ill patients in the ICU within 90 days of admission.³ The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight, presence of pulmonary rales, and edema), blood chemistry, natriuretic peptides, liver enzymes, hemoglobin and hematocrit, blood volume analysis, and/or bioimpedance analysis.⁴ Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema⁵ and is a leading cause of hospital readmissions with patients suffering from heart failure and patients following cardiac surgery.⁶

The condition of fluid overload is often observed in patients with heart failure and secondary oliguric states,⁷ although in pediatric patients, fluid overload is associated with significant increases in mortality.^{8,9} Congestion or fluid overload, the hallmark of decompensated HF, is the primary reason for hospitalization in 90% of these patients.^{10,11} For this reason, diuretics have been the cornerstone of heart failure treatment for more than 50 years.¹² Over the past 20 years, approaches to treatment have changed dramatically.¹³ These dramatic improvements include new medications and new technologies, such as ultrafiltration, to help treat fluid

¹ Murugan R et al. *Nature Rev Nephrol.* 2020; 1-14.

² Koratala A et al. *Cardiorenal Med.* 2022;12(4):141-154.

³ Vaara ST et al. *Crit Care.* 2012; 16: 1-11.

⁴ Koratala A et al *Cardiorenal Med.* 2022;12(4):141-154

⁵ Stein, A, et. al. *Critical Care,* 2012:16:R99.

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

⁷ Ronco C, Costanzo MR, Bellomo R, et al. (2010) *Fluid Overload Diagnosis and Management.* Basel, Switzerland: Karger.

⁸ Sutherland SM, et al. *Am J Kidney Disease.* 2010; 5(2): 316-25.

⁹ Gillespie RS, et al. *Ped Nephro.* 2004; 19(12): 1394-99.

¹⁰ Kazory A & Costanzo MR. *Adv Chronic Kidney Dis.* 2018; 25(5): 434-442.

¹¹ Fonarow GC. *Rev Cardiovasc Med.* 2003; 4: s21-30.

¹² Kamath SA. *Int J of Nephrol.* 2011; 1-6.

¹³ Ellison DH. *Cardio.* 2001;96:132-143

overload. Each year there are over 1 million heart failure hospitalizations in the United States, and 90% of those hospitalizations are due to symptoms of fluid overload.¹⁴ These patients are hospitalized on average for 8.3 days at a cost of approximately \$24,000¹⁵, to which reimbursement will only cover about 34%¹⁶ of that cost. On top of that, there is a 30-day readmission penalty for which the hospitals absorb another cost but do not get reimbursed with some data suggesting such penalties can cost a hospital up to \$15.2 million annually.^{17, 18, 19}

Treatments for Fluid Overload

Diuretics

Treatment for fluid overload has traditionally been achieved through use of oral or loop diuretics which may be accompanied by use of other categories of medications, such as ACE inhibitors, beta-blockers, and inotropic drugs. Chronic diuretic use has been associated with increased long-term mortality and hospitalizations in a wide spectrum of chronic systolic and diastolic HF patients.²⁰ Increasing concern exists that diuretics, particularly at high doses, may be deleterious in the inpatient setting. Diuretics have a variable dose response rate and studies have shown nearly 70% of heart failure patients treated with diuretics have a suboptimal response.^{21, 22} Additionally, between 10-40% of heart failure and cardiac surgery patients are refractory to diuretics,²³ with diuretic resistance associated with a higher risk of in-hospital worsening of heart failure, increase mortality after discharge, and a 3-fold increase in rehospitalization rates.²⁴ In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.²⁵ Also, long term use of diuretics has been associated with kidney damage.²⁶ Approximately 40% of heart failure patients have poor diuretic response.²⁷ 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.²⁸ Despite treatment with loop diuretics, patients are frequently hospitalized and treated for recurrent symptoms and signs of fluid overload. Among more than 50,000 patients enrolled in the Acute Decompensated Heart Failure National Registry (“ADHERE”) study, only 33% lost \geq 2.27 kg. (5 lbs.), and 16% gained weight during hospitalization.²⁹

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.³⁰ Additionally, one study found that 24% of such patients were readmitted to the hospital within 30 days of their discharge, and up to 42-50% were readmitted at 90 days and 6 months respectively.^{31, 32} 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.³³ There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.³⁴ Therefore, an alternative therapy to help stabilize or improve patient care is needed.

¹⁴ Costanzo MR, et al. *J Am Coll Cardiol.* 2017 May 16;69(19):2428-2445.

¹⁵ From Premier Applied Sciences database.

¹⁶ Reimbursement estimates from MCRA.

¹⁷ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-2445.

¹⁸ McIlvennan CK, Eapen ZJ, Allen LA. *Circulation.* 2015 May 19;131(20):1796-803.

¹⁹ From Premier Applied Sciences database.

²⁰ Ahmed A, et al. *Eur Heart J.* 2006 Jun;27(12):1431-9.

²¹ Kazory A & Costanzo MR. *Adv Chronic Kidney Dis.* 2018; 25(5): 434-442; 30.

²² Testani JM, Hanberg JS, Cheng S et al. *Circ Heart Fail.* 2016; 9(1): e002370.

²³ Testani JM, Hanberg JS, Cheng S et al. *Circ Heart Fail.* 2016; 9(1): e002370.

²⁴ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-2445.

²⁵ Kamath SA. *Int J of Nephrol.* 2011: 1-6.

²⁶ Felker MG & Mentz RJ. *J Am Coll Cardiol.* 2012;59(24):2145-53.

²⁷ Testani JM. *Circ Heart Fail.* 2016 Jan;9(1):e002370.

²⁸ Hoorn EJ & Ellison DH. *Am J Kidney Dis.* 2017;69(1):136-142.

²⁹ Gheorghiadu M, et al. *Eur Heart J Suppl.* 2005; 7:B13– 19.

³⁰ Orso D, et al. *Eur Rev Med Pharmacol Sci.* 2021 Apr;25(7):2971-2980.

³¹ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428- 2445.

³² Thandra A, et al. *Clin Invest.* 2023; 365(2): 145-51.

³³ Felker GM, et al. *N Engl J Med.* 2011; 364:797–805.

³⁴ Costanzo MR, et al. *J Am Coll Cardiol.* 2007; 49(6):675-683.

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 20 years.³⁵ Ultrafiltration is a safe and effective therapy to treat fluid overload and congestion by removing extra fluid and salt.³⁶ With ultrafiltration, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The use of ultrafiltration therapy in subgroups of patients, such as heart failure and post-cardiac surgery, has demonstrated clinical benefits in treating fluid overload signs and symptoms. 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 isotonic fluid (primarily excess salt and water) from patients suffering from fluid overload who have failed diuretic therapy.

With the Aquadex System, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The Aquadex System has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate.^{38, 39} 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. The Company estimates it has treated nearly 26,000 patients across all three (3) of our customer categories, since it reintroduced the Aquadex System to the U.S. market in 2016.

Benefits of the Aquadex System

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

- Reduces hospitalization by 81%⁴⁰ compared to diuretics;
- Rehospitalizations with Aquadex were 48% lower than the national average at 30 days,⁴¹
- Reduces length of hospital stay when initiated early, resulting in average savings of \$3,975 (14%);⁴²
- Stabilizes or improves cardiac hemodynamics;^{43, 44}
- Safe, easy-to-use, and flexible in application;
- Provides complete 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;
- Can be performed via peripheral or central venous access;
- Predictably removes excess isotonic fluid (extracts water and sodium while sparing potassium and magnesium; decrease risk of electrolyte abnormalities);^{45, 46}

³⁵ Agostoni PG, et al. *J Am Coll Cardiol*. 1993; 21(2):424-431.

³⁶ Kazory A, et al. *Cardiorenal Med*. 2023;13(1)1-8.

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

³⁸ SAFE Trial: Jaski BE, et al. *J Card Fail*. 2003; 9(3): 227-231.

³⁹ RAPID Trial: Bart BA, et al. *J Am Coll Cardiol*. 2005; 46(11): 2043-2046.

⁴⁰ Watson R et al. *Am Heart J Plus: Cardiol: Res & Pract*. 2022; 242:1-6.

⁴¹ Watson R et al. *Am Heart J Plus: Cardiol: Res & Pract*. 2022; 242:1-6.

⁴² Costanza MR, et al. *Value Health*. 2018; 21 (Suppl 1):S167.

⁴³ Boga M, et al. *Perf*. 2000; 15:143-150.

⁴⁴ Kiziltepe U, et al. *Ann Thorac Surg* 2001;71:684-93.

⁴⁵ Kazory A, et al. *Cardiorenal Med*. 2023;13(1)1-8.

⁴⁶ Agostoni PG et al. *J Am Coll Cardiol*. 1993;21(2):424-31.

- No significant changes to kidney function,⁴⁷
- The use of continuous hematocrit monitoring and SvO₂ sensor provides guided-therapy ultrafiltration.⁴⁸
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored,⁴⁹
- Provides highly automated operation with only one setting required to begin therapy;
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up; and
- Has a built-in console that guides the medical practitioner through the setup and operational process.

Components of the Aquadex System

The Aquadex System consists of:

- A console, a piece of capital equipment containing electromechanical pumps, an LCD screen and stand;
- A one-time disposable blood circuit set, 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, 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.

Our Market Opportunity

The Aquadex System is indicated for the treatment of patients suffering from fluid overload who have failed medical therapy including diuretics, or patients that can benefit from a predictable mechanical way to remove excess fluid (isotonic fluid). We are currently focusing our commercial activities in three primary clinical areas where fluid overload is prevalent: heart failure, critical care and pediatrics.

Heart Failure

Heart disease is the leading cause of death in the United States and other developed countries. In fact, approximately 50% of patients who develop heart failure die within five years of diagnosis. The five-year mortality rate for heart failure, regardless of heart function, is approximately 75% across all phenotypes.⁵⁰ Approximately 6.7 million Americans over 20 years of age have heart failure, and the prevalence is expected to rise to 8.5 million Americans by 2030.⁵¹ Based on the Atherosclerosis Risk in Communities Study from 2005 to 2013, conducted by the National Heart, Lung and Blood Institute, there are an estimated 960,000 new heart failure cases annually.⁵² Annual hospitalizations for heart failure exceed one million in both the United States and Europe, and more than 90% are due to symptoms and signs of fluid overload.⁵³ In addition, approximately 68% of patients are discharged with sub-optimal results.⁵⁴ As such, there are over 600,000 heart failure patients in the United States who might benefit from new technologies to treat fluid overload.

Heart failure is a syndrome that can have an acute onset or is a progressive disease caused by impairment of the heart's ability to pump blood to the various organs of the body. Patients with heart failure and fluid overload commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The heart becomes weak or stiff and enlarges over time, making it harder for the heart to pump the blood needed for the body to function properly. The severity of heart failure depends on how well a person's heart pumps blood throughout the body.⁵⁵

⁴⁷ Kazory A, et al. *Cardiorenal Med.* 2023;13(1)1-8.

⁴⁸ Starr MC, et al. *Pediatric Nephrology.* 2024; 39(2):597-601.

⁴⁹ Costanzo MR, et al. *J Am Coll Cardiol.* 2005; 46(11): 2047-51.

⁵⁰ Shah, K, et al. *J Am Coll Cardiol.* 2017 Nov, 70 (20) 2476–2486.

⁵¹ Bozhurt B, et al. *J Card Fail. J Card Fail.* 2023; 29(10): 1412-42.

⁵² Benjamin EJ, et al. *Circ.* 2017;135:00-00. (e378).

⁵³ Fonarow GC, et al. *Rev Cardiovasc Med.* 2003; 4: s21-30.

⁵⁴ Testani JM, et al. *Circ Heart Fail.* 2016; 9(1): e002370.

⁵⁵ Arrigo M et al. *Nat Rev Dis Primers.* 2020; 6(16):1-15.

According to a nationwide study of over 140,000 patients suffering from acute decompensated heart failure, over 38% of patients discharged were still symptomatic and about half of the patients were discharged with less than five pounds lost.⁵⁶ This clinical evidence from the ADHERE registry shows patients are discharged too early, while still showing evidence of fluid overload.

As a result of not fully having their fluid imbalance properly addressed prior to discharge from the hospital, patients are frequently being readmitted, with 30-day readmissions of 24% and 6-month readmissions of 44%, while 80% of patients are admitted directly to the emergency department as the first point of care.^{57, 58}

Heart failure often requires inpatient treatment, and it carries a huge economic burden in the United States, costing the nation an estimated \$60.2 billion each year, with hospital costs accounting for 62% of the economic burden.⁵⁹ As the population ages, healthcare expenditures are expected to increase substantially.⁶⁰ Therefore, therapies aimed at treating congestion and fluid overload are essential from a patient care and healthcare economics perspective.

To remove the excess fluid, patients suffering from heart failure may receive ultrafiltration therapy in two settings: (i) *inpatient care*: provided to a patient admitted to a hospital, extended care facility, nursing home or other longer-term care facility; and (ii) *outpatient care*: provided to a patient who is not admitted to a facility, but receives treatment at a doctor's office, clinic, or hospital outpatient department.

Hospitals in the United States also face potential penalties for heart failure readmissions. As part of the Patient Protection and Affordable Care Act of 2012, as amended (the "Affordable Care Act"), Medicare instituted the Hospital Readmissions Reduction Program (HRRP), which penalizes hospitals with high 30-day readmission rates for heart failure and other common diseases and procedures. This penalty can be as high as 3% of reimbursement for all Medicare admissions. Technologies that help reduce readmissions, such as the Aquadex System, can help hospitals mitigate these penalties.⁶¹

The Company believes the total U.S. heart failure market is approximately \$1 billion⁶² and that roughly 30% of its revenue is derived from the treatment of heart failures patients.

Critical Care

Patients suffer from fluid overload in connection with a variety of critical care procedures and treatments, including cardiac surgery, cardiogenic shock, liver and other organ transplants, ventricular assist device ("VAD") implants, extra corporeal membrane oxygenation ("ECMO") therapy, sepsis, liver disease and severe burns. According to the National Center for Health Sciences, over 7.3 million cardiovascular operations are performed each year in the United States, including an estimated 340,000 coronary-artery bypass grafting (CABG) procedures,⁶³ 180,000 valve procedures,⁶⁴ and 3,000 VAD implants.⁶⁵ Cardiac surgery is associated with a degree of fluid overload due to cardiopulmonary bypass.⁶⁶ Intravenous fluid therapy is an integral treatment for patients undergoing surgery and in critical care units.⁶⁷ Fluid overload in post-cardiac surgery can readily occur because surgery can affect the pumping actions of the heart, leading to postoperative hemodynamic instability.⁶⁸ The condition often remains symptomless for several days until clinical symptoms become apparent, when treatment is almost always too late and ineffective.⁶⁹

⁵⁶ Fonarow et al. *Rev Cardiovasc Med*. 2003;4: Suppl 7:S21-30.

⁵⁷ Costanzo MR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445.

⁵⁸ Sax D, et al. *J Card Fail*. 2022; 28(10): 1545-59.

⁵⁹ Voigt J, et al. *Clin Cardiol*. 2014;37(5): 312-321.

⁶⁰ Heidenreich PA, et al. *Circ Heart Fail*. 2013;6(3):606-619.

⁶¹ McIlvennan C et al. *Circ*. 2015; 131(20): 1796-1803.

⁶² See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

⁶³ <https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/>.

⁶⁴ <https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/>.

⁶⁵ Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.

⁶⁶ Kruger A et al. *J Cardiovasc Dev Dis*. 2023;10(6):263-78.

⁶⁷ Bowdish ME, et al. *Ann Thorac Surg*. 2021;111(6):1770-1780.

⁶⁸ Xu J, et al. *Medicine*. 2015;94(33):e1360.

⁶⁹ Xu J, et al. *Medicine*. 2015;94(33):e1360.

The potential complications (e.g., renal failure, stroke, infection, arrhythmias, or prolonged intubation) are reported to be associated with high mortality, particularly when renal replacement therapy is required.⁷⁰ Major complications after cardiac operations are associated with an increased risk for operative death, longer hospital length of stay, and higher rates of discharge to a location other than home.⁷¹ Hospital readmissions are a common problem in cardiac surgery and remain high. Approximately 20% of patients who undergo cardiac operations require readmission, an outcome with significant health economic implications. Volume overload was among the top three most prevalent causes for first readmission within 30 days and beyond 30 days.⁷² It is estimated that 13.5% of post cardiac surgery patients are readmitted due to fluid overload within 30 days of discharge, which equates to an estimated 70,000 fluid overload-related readmissions for CABG, valve, and VAD procedures per year in the United States.⁷³ Positive research has been recently published demonstrating the value of ultrafiltration in high-risk coronary artery bypass grafting surgery.⁷⁴ It is also encouraging to see ultrafiltration being recommended for cardiac surgery patients who are unresponsive to diuretics in a recently published turnkey order set proposed by the ERAS Society consensus guidelines.⁷⁵

The Company believes it can expand use cases for the Aquadex System, without any additional clinical trial or other labeling changes at the FDA to support its use in the applications identified immediately above.

The Company believes the total U.S. critical care failure market is approximately \$900 million⁷⁶ and that approximately 40% of its revenue is derived from the treatment of critical care patients.

Pediatrics

Many of the conditions and procedures faced by adult patients also occur in pediatric patients, such as cardiac surgery, organ transplants, heart failure and ECMO therapy. Similar to adult patients, these conditions and procedures may lead to fluid overload. While incidence data is not readily available, it is estimated that there are approximately 10,000 to 14,000 pediatric patients with heart failure⁷⁷ and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation.^{78, 79, 80} Fluid overload drives pediatric morbidity and mortality risk in critically ill patients. In one pediatric study, a 3% increase in mortality was observed for every 1% increase in fluid overload, and children who are more than 20% fluid overloaded have an odds ratio for mortality of 8.5 compared to children who are less than 20% fluid overloaded.^{81, 82}

The Company believes that the total U.S. pediatric market for fluid overload is approximately \$130 million⁸³ and that roughly 30% of its revenue is derived from the treatment of pediatric patients.

While the Aquadex System is only FDA cleared for the treatment of pediatric patients weighing 20 kgs or more, the Company is aware that many children's hospitals in the U.S. are modifying the way that the Aquadex System is used in a manner that is deemed to be off-label by the Company and FDA in order to provide dialysis to neonates and other premature infants who weigh less than 20 kilograms and who were born either without kidneys or without normal kidney function. These patients typically have very few other treatment options given the large extracorporeal blood volume required by standard dialysis machines the need for blood priming of the dialysis circuit and the use of large catheters. By comparison, the Aquadex extracorporeal blood volume is only 35 milliliters.

⁷⁰ Granado RC et al. *BMC Nephro.* 2016;17:109-18.

⁷¹ Crawford TC, et al. *Ann Thorac Surg.* 2017;103:32-40.

⁷² Iribane A, et al. *Ann Thorac Surg.* 2014;98:1274-80.

⁷³ Iribane A, et al. *Ann Thorac Surg.* 2014 Oct; 98(4): 1274-80.

⁷⁴ Beckles DL et al. *J Card Surg.* 2022; 37: 2951-57.

⁷⁵ Engelman D, et al. *Ann Thorac Surg.* 2023;115:11-5A

⁷⁶ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

⁷⁷ Jayaprasad, N. *Heart Views.* 2016; 17(3): 92-99.

⁷⁸ <https://www.cdc.gov/ncbddd/heartdefects/data.html>.

⁷⁹ Karamlou T, et al. *J Thorac Cardiovasc Surg.* 2013 Feb; 145(2):470-5.

⁸⁰ <https://www.organdonor.gov/about/donors/child-infant.html>.

⁸¹ Sutherland SM, et al. *Am J Kidney Dis.* 2010; 55(2):315-25.

⁸² Gillespie RS, et al. *Ped Nephro.* 2004; 19(12):1394-99.

⁸³ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

It is because of this unmet medical need the Company has undertaken the development of a dedicated CRRT device intended for patients weighing between 2.5 and 10 kilograms. See – Product Development Activities below.

Growing Clinical Evidence

In December 2021, we launched the REVERSE-HF prospective, multicenter, randomized controlled trial (RCT) to evaluate ultrafiltration compared to IV diuretics in patients with heart failure. This RCT is currently being conducted at sixteen clinical sites nationwide, and patient enrollment began in June 2022. As of December 31, 2023, there are 80 patients enrolled in this RCT. The primary effectiveness endpoint is the time to first Heart Failure (HF) Event within 30 days, as a comparison between Aquadex therapy and IV Loop Diuretics. The Company intends to target a total of 20 sites and hopes to be fully enrolled by the end of 2024 with a total of 372 patients enrolled. The protocol for REVERSE-HF permits an interim data analysis once enrollment reaches 80% of its targeted enrollment, and the Company hopes to complete analysis and to publish the results of the study in the second half of 2025.

Secondary endpoints will be analyzed as a comparison between Aquadex and IV Loop Diuretics:

- Composite win ratio analysis of Cardiovascular (CV) mortality, HF events, and quality of life within 30 days:
 - CV mortality
 - HF event
 - Change in Kansas City Cardiomyopathy Questionnaire (KCCQ) score
- Time to first HF event within 90 days
- Time to first HF event or all-cause death within 90 days
- HF events within 30 and 90 days
- Treatment crossovers

In December 2022, a third-party, real-world retrospective study of 335 patients treated with the Aquadex FlexFlow® System, “*Ten Year Experience with Ultrafiltration for the Management of Acute Decompensated Heart Failure*,”⁸⁴ compared previous randomized controlled clinical trials with ultrafiltration and demonstrated that ultrafiltration compares favorably in reducing heart failure rehospitalizations, renal function response, and weight/volume loss. The study found ultrafiltration to be safe with regard to renal function despite the cohort in this study being sicker than those studied in other clinical trials, and that Ultrafiltration can be a safe and effective strategy for decongestion in clinical practice wherein the benefits outweigh the potential risks of kidney dysfunction requiring hemodialysis and major bleeding events.⁸⁵ Additionally, another 2022 peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients.⁸⁶ Jain et al. pooled data from seven randomized controlled trials of ultrafiltration with a total of 771 patients and concluded that extracorporeal ultrafiltration is associated with more efficient fluid and sodium removal compared with medical therapy, hence leading to a reduction in readmission rates and a potential salutary impact on financial burden associated with the care of heart failure patients.⁸⁷ Compared to diuretics, ultrafiltration provided predictable, adjustable, and more efficient fluid removal – without clinically adverse impacts on renal function, demonstrating a 14% cost reduction at 90-days achieved due to reduced readmissions.⁸⁸

The AVOID-HF trial was initiated by Baxter in 2016. AVOID-HF was designed to prospectively address the question of patient outcomes when treated with ultrafiltration versus intravenous diuretics for acute decompensated heart failure. Trial design assumptions indicated that 810 patients would need to be randomized to achieve adequate statistical power. However, the study was terminated by Baxter at 224 patients, apparently for business reasons unrelated to patient outcomes or device safety. Despite being underpowered, the results of

⁸⁴ Watson R, et al. *Am Heart J Plus: Cardiol Res & Pract* 24. 2022; 1-6.

⁸⁵ Watson R, et al. *Am Heart J Plus: Cardiol Res & Pract* 24. 2022; 1-6.

⁸⁶ Kazory et al. *Cardiorenal Med.* 2023;13:1-8.

⁸⁷ Kazory A, et al. *Cardio Renal Med.* 2023.12(1):1-8.

⁸⁸ Costanzo MR, et al. *Val in Health.* 2018; 21(1): s167.

AVOID-HF indicated distinct trends toward reduced time to heart failure events within 90 days, favoring the ultrafiltration group over diuretics. In addition, pre-specified secondary endpoints demonstrated significant reductions in heart failure rehospitalizations and days in the hospital and cardiovascular events at 30 days. No significant differences were observed in creatinine level between the groups during treatment and up to 90 days following treatment. In totality, AVOID-HF provided evidence that had AVOID-HF been followed to completion, it is our belief that the trial would likely have met its primary endpoint of improved outcome in acute decompensated heart failure patients.⁸⁹

One 2019 peer reviewed paper reported on a multicenter, retrospective case series of children who received kidney replacement therapy (KRT) with an ultrafiltration device.⁹⁰ Patients were grouped according to weight and primary disease state (e.g. kidney, cardiac or other) and received one of three treatment modalities. The study found that of the 72 patients who weighed less than 10 kg, 43 or 60% survived to the end of therapy or transitioned to another modality of kidney support. 23 or 32% survived to hospital discharge. Among patients who weighed between 10-20 kg, 13 or 100% survived to the end of KRT treatment. Among patients who weighed more than 20 kg, 33 or 97% survived to KRT discontinuation and 23 or 68% survived to hospital discharge.⁹¹

Product Development Activities

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

Corporate Development Activities

DaVita Supply and Collaboration Agreement

On June 19, 2023, we entered into a Supply and Collaboration Agreement (the “Supply Agreement”) with DaVita Inc., a Delaware corporation (“DaVita”), pursuant to which DaVita agreed to pilot the Aquadex ultrafiltration therapy system to treat adult patients with congestive heart failure and related conditions within select U.S. markets. The pilot program launched in June 2023 and extends through May 31, 2024 (the “Pilot”). Through the Pilot, ultrafiltration therapy using Aquadex will be offered at a combination of DaVita’s customer hospital and outpatient center locations, with both companies collaborating on the roll-out of the therapy, clinician training, and patient support. At the conclusion of the pilot, DaVita has the option, in its sole discretion, to extend the Supply Agreement with the Company for continued provision of both inpatient and outpatient ultrafiltration services for up to 10 years (“Ultrafiltration Services Approval”). DaVita reports that it has over 900 hospital partnerships, 2,500 clinics, over 6,500 employees and revenue of approximately \$11.6 billion for its 2022 fiscal year.

SeaStar License and Distribution Agreement

On December 27, 2022, we entered into an exclusive license and distribution agreement (the “Distribution Agreement”) with SeaStar Medical Holding Corporation (“SeaStar”), pursuant to which SeaStar appointed the Company as its exclusive distributor for the sale and distribution of SeaStar’s Selective Cytopheretic Device (“SCD-PED”) product throughout the United States following the receipt by SeaStar from the FDA of a written authorization to market such product for pediatric use pursuant to the Humanitarian Device Exemption (HDE) application submitted by SeaStar. The SCD-PED will provide a new therapy option for children weighing 10 kilograms or more who have acute kidney injury (AKI) and sepsis or a septic condition requiring continuous kidney replacement therapy (CKRT) in a hospital intensive care unit.

⁸⁹ Costanzo MR, et al. *JACC: Heart Failure*. 2016;4(2):95-105.

⁹⁰ Menon S, et al. *Clin J Am Soc Nephrol*. 2019;14(10):1432-1440.

⁹¹ Menon S, et al. *Clin J Am Soc Nephrol*. 2019;14(10):1432-1440.

Pursuant to the Distribution Agreement, SeaStar received an upfront payment, and is entitled to milestone payments upon achievement of certain milestones and royalties on gross sales of the SCD- PED product. The Distribution Agreement has an initial term commencing on December 27, 2022 and shall end on the three (3) year anniversary from the date that is the earlier of (a) ninety (90) days after SeaStar receives FDA authorization to market such SCD- PED product for pediatric use and (b) the first commercial sale of the SCD-PED product. The term of the Distribution Agreement may be automatically extended for additional terms of one (1) year and for a total of two (2) extensions. Each party has the right to terminate the Distribution Agreement for material breach if such breach is not cured within ninety (90) days after written notice. SeaStar has additional rights to terminate the Distribution Agreement in accordance with other terms set forth in the Distribution Agreement.

On October 31, 2023, we announced that SeaStar received an Approvable Letter from the FDA for its SCD-PED. The Approvable Letter indicated that SeaStar Medical's HDE application substantially meets the requirements for an Approval Order and outlined remaining administrative steps that must be finalized before the HDE can be active for commercialization. For the SCD-PED, these include revisions to product labeling and minor modifications to the post-approval study plan.

Recent Developments

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

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from December 7, 2023, or until June 4, 2024, to regain compliance with the Minimum Bid Price Requirement. If at any time before June 4, 2024, the closing bid price of 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 June 4, 2024, 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 June 4, 2024, 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.

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 control over financial reporting.

	The Offering
Issuer	Nuwellis, Inc.
Units to be Offered	Up to 16,326,530 units, with each unit consisting of one share of common stock and one common warrant to purchase one share of common stock.
Pre-funded Units to be Offered	We are also offering to certain purchasers whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, in lieu of units the opportunity to purchase, if such purchasers so choose, pre-funded units, consisting of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase one share of common stock. The purchase price of each pre-funded unit will equal the price per unit being sold to the public in this offering, minus \$0.0001, and the exercise price of each pre-funded warrant will be \$0.0001 per share of common stock. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. This offering also relates to the shares of common stock issuable upon the exercise of any pre-funded warrants or common warrants comprising the pre-funded unit sold in this offering.
Description of Common Warrants	Each common warrant will have an exercise price of \$0.49 per share (equal to 100% of the assumed public offering price of each unit sold in this offering), will be immediately exercisable, and will expire on the five (5) year anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.
Common Stock Outstanding before this Offering	5,682,461 shares of common stock as of December 31, 2023.
Common Stock Outstanding after this Offering	Up to 22,008,991 shares (assuming the sale of the maximum number of units covered by this prospectus, no sale of pre-funded units, and no exercise of the common warrants included in the units issued in this offering).
Use of Proceeds	Assuming the maximum number of units are sold in this offering at an assumed public offering price of \$0.49 per unit, which represents the closing price of our common stock on the Nasdaq Capital Market on January 26, 2024, and assuming no issuance of pre-funded units in connection with this offering, we estimate that the net proceeds from our sale of units in this offering will be approximately \$7.0 million, after deducting the placement agent fees and estimated offering expenses payable by us. However, this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, and we may not sell all or any of these securities offered pursuant to this prospectus; as a result, we may receive significantly less in net proceeds. We intend to use the net proceeds of this offering for working capital and for

	<p>general corporate purposes, including for continued investments in our commercialization efforts. For additional information please refer to the section entitled “Use of Proceeds” on page 36 of this prospectus.</p>
Risk Factors	<p>Investing in our securities involves a high degree of risk and purchasers of our securities may lose their entire investment. See the information under the captions “Summary of Risk Factors” and “Risk Factors” beginning on page 15 and 17, respectively, of this prospectus and the other information included elsewhere in this prospectus for a discussion of factors you should consider before deciding to invest in our securities.</p>
Listing of Common Stock	<p>Our common stock is listed on the Nasdaq Capital Market under the ticker symbol “NUWE”. There is no established trading market for the common warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the common warrants or the pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the common warrants and the pre-funded warrants will be extremely limited.</p>
Reasonable Best Efforts Offering	<p>We have agreed to offer and sell the securities offered hereby to the purchasers through the placement agents. The placement agents are not required to buy or sell any specific number or dollar amount of the securities offered hereby, but they will use their reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. See “Plan of Distribution (Conflicts of Interest)” beginning on page 100 of this prospectus.</p>
Conflicts of Interest	<p>Lake Street, a placement agent in this offering, has a “conflict of interest” under Rule 5121 of FINRA because one of our directors is the head of Life Science Investment Banking and a Managing Director of Lake Street. Accordingly, Maxim has agreed to act as a “qualified independent underwriter” within the meaning of FINRA Rule 5121 in connection with this offering. In its role as a qualified independent underwriter, Maxim has participated in the preparation of this registration statement and the prospectus and has exercised the usual standards of due diligence with respect thereto. For a more complete discussion of the role and compensation of the placement agents, please see the section of this prospectus entitled “Plan of Distribution (Conflicts of Interest).”</p>
	<p>Except as otherwise indicated, all information in this prospectus is based on 5,682,461 shares of common stock outstanding as of December 31, 2023 and excludes the following:</p> <ul style="list-style-type: none"> • 110,916 shares of our common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$35.90 per share; • 2,963,192 shares of our common stock issuable upon the exercise of outstanding warrants (other than the warrants offered hereby) with a weighted-average exercise price of \$30.86 per share; • 125,857 shares of our common stock issuable upon the conversion of the 127 outstanding shares of our Series F Preferred Stock; • 295,792 shares of our common stock issuable upon the conversion of the 11,950 outstanding shares of our Series J Convertible Preferred Stock;

- 1,656,361 shares of our common stock issuable upon conversion of 66,917 Series J Convertible Preferred Stock issuable upon the exercise of 133,834 warrants issued in the October 2023 Offering; and
- 41,871 shares of our common stock reserved for future issuance under our equity incentive plans.

To the extent that additional shares of common stock are issued upon the exercise of outstanding options or warrants, or the conversion of our outstanding Series F Convertible Preferred Stock, Series J Convertible Preferred Stock, or the vesting of restricted stock units or additional grants are made pursuant to our equity incentive plans, there will be dilution to new investors. All share and per share amounts for all periods presented in this prospectus and the registration statement of which it forms a part have been retroactively adjusted to reflect the reverse stock splits we previously effected on January 12, 2017, October 12, 2017, January 2, 2019, October 16, 2020 and December 9, 2022.

Unless otherwise indicated, this prospectus assumes no issuance of pre-funded units in connection with this offering and no exercise of the common warrants offered hereby.

SUMMARY OF RISK FACTORS

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

- We have limited history of operations and limited experience in sales and marketing, and we might be unsuccessful in increasing our sales and cannot assure you that we will ever generate substantial revenue or be profitable.
- We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near-term. To date, we have been funded by equity financings, and although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably. 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 through the end of fiscal year 2024. If additional capital is not available, we will have to delay, reduce or cease operations. These factors raise substantial doubt about the Company's ability to continue as a going concern through the next twelve months.
- Our near-term prospects are highly dependent on revenues from a single product, the Aquadex System. We face significant challenges in expanding market acceptance of the Aquadex System, which could adversely affect our potential sales.
- Nasdaq may delist our common stock from its exchange which could limit your ability to make transactions in our securities and subject us to additional trading restrictions.
- We depend on a limited number of customers, the loss of which, or failure of which to order our products in a particular period, could cause our revenues to decline.
- We have limited commercial manufacturing experience and could experience difficulty in producing commercial volumes of the Aquadex System and related components or may need to depend on third parties for manufacturing.
- We depend upon third-party suppliers, including single source suppliers, making us vulnerable to supply problems and price fluctuations.
- The COVID-19 outbreak and other public health threats or outbreaks of communicable diseases could have a material adverse effect on our operations and overall financial performance.
- We have been negatively impacted by the prioritization of COVID-19 patients in hospitals.
- If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute the Aquadex System effectively and our sales will suffer.
- We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.
- The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.
- Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales.
- Product defects, resulting in lawsuits for product liability, could harm our business, results of operations and financial condition.
- We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations.
- If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the European Union, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales will suffer.
- If we violate any provisions of the Federal Food, Drug, and Cosmetic Act ("FDC Act") or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.

- We cannot assure you that our products will be safe or that there will not be serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.
- We face significant uncertainty in the industry due to government healthcare reform.
- We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.
- Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws could subject us to penalties and other adverse consequences.
- If we acquire other businesses, products or technologies, we could incur additional impairment charges and will be subject to risks that could hurt our business.
- We may not be able to protect our intellectual property rights effectively, which could have an adverse effect on our business, financial condition or results of operations.
- Intellectual property litigation could be costly and disruptive to us.
- If we were unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and system could be adversely affected.
- Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- The trading price of our common stock price has been, and could continue to be, volatile.
- The rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of our outstanding preferred stock and stock that may be issued in the future.
- A more active, liquid trading market for our common stock may not develop, and the price of our common stock may fluctuate significantly.
- If we do not comply with certain tax regulations, including VAT, and similar regulations, we may be subject to additional taxes, customs duties, interest, and penalties in material amounts, which could materially harm our financial condition and operating results.
- Our ability to use U.S. net operating loss carryforwards and other tax attributes might be limited.
- We do not intend to pay cash dividends on our common stock in the foreseeable future.
- There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.
- This is a best-efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

RISK FACTORS

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this prospectus. Any of the risks and uncertainties set forth herein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment in our securities. Additional risks and uncertainties not presently known or which we consider immaterial as of the date hereof may also have an adverse effect on our business.

RISKS RELATED TO THIS OFFERING AND OUR COMMON STOCK

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

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

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

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

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

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

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

The number of shares of common stock underlying the securities we propose to issue and ultimately will issue if this offering is completed, may result in an immediate decrease in the market price of our common stock.

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This decrease may continue after the completion of this offering. We cannot predict the effect, if any, that the availability of shares for future sale represented by the pre-funded warrants or common warrants issued in connection with the offering will have on the market price of our common stock from time to time.

Lake Street may have a “conflict of interest” under FINRA Rule 5121.

Lake Street, a placement agent in this offering, has a “conflict of interest” under Rule 5121 of FINRA because one of our directors is the head of Life Science Investment Banking and a Managing Director of Lake Street. Accordingly, this offering will be made in compliance with the applicable provisions of Rule 5121. The rule requires that a “qualified independent underwriter” meeting certain standards participate in the preparation of the registration statement and prospectus and exercise the usual standards of due diligence with respect thereto. Maxim has agreed to act as a “qualified independent underwriter” within the meaning of Rule 5121 in connection with this offering. In its role as qualified independent underwriter, Maxim has participated in due diligence and the preparation of this prospectus and the registration statement of which this prospectus forms a part and has exercised the usual standards of due diligence with respect thereto. See the section of this prospectus captioned “Plan of Distribution (Conflicts of Interest)” for additional information.

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

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

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

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

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company has a period of 180 calendar days from December 7, 2023, or until June 4, 2024, to regain compliance with the Minimum Bid Price Requirement. If at any time before June 4, 2024, the closing bid price of 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 June 4, 2024, 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 June 4, 2024, 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.

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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.

On December 9, 2022, we effected a 1-for-100 reverse stock split of our outstanding common stock. All share amounts and warrant or option exercise prices contained in this report reflect that adjustment. Additionally, in 2020, the SEC approved a Nasdaq rule change to expedite delisting of securities of companies that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two-year period. Under the new rules, if a company falls out of compliance with the \$1.00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any compliance periods and Nasdaq will instead require the issuance of a Staff delisting determination, which is appealable to a hearings panel. Our ability to remain listed on the Nasdaq Capital Market may be negatively impacted by this new Nasdaq rule.

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

Each common warrant has an exercise price of \$0.49 per share (equal to 100% of the assumed public offering price of each unit sold in this offering), and may also be exercised in certain circumstances by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the warrant. Accordingly, we may not receive any additional funds, or any significant additional funds, upon the exercise of the warrants.

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

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

The common warrants included in the units and in the pre-funded units are speculative in nature.

The common warrants represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the common warrants may acquire the shares of common stock issuable upon exercise of such warrants at an exercise price of \$0.49 per share of common stock (equal to 100% of the assumed public offering price of each unit sold in this offering). Moreover, following this offering, the market value of the common warrants is uncertain and there can be no assurance that the market value of the common warrants will equal or exceed the public offering price. There can be no assurance that the market price of the shares of common stock will ever equal or exceed the exercise price of the common warrants, and consequently, whether it will ever be profitable for holders of common warrants to exercise the common warrants.

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

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

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

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims for breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including timely delivery of shares and indemnification for breach of contract.

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

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

As of December 31, 2023, we have warrants to purchase 2,963,192 shares of common stock outstanding, with exercise prices ranging from \$3.30 to \$189,000 with a weighted-average exercise price of \$30.86.

As of December 31, 2023, there were 127 shares of Series F Preferred Stock outstanding, convertible into 125,857 shares of common stock. The certificate of designation for our Series F Preferred Stock contains an anti-dilution provision, which provision requires the lowering of the applicable conversion price, as then in effect, to the purchase price per share of common stock or common stock equivalents issued in the future. If the effective price per share on a common-stock equivalent basis in a future equity offering is lower than the then-current conversion price of the Series F Convertible Preferred Stock, then such conversion price shall be reduced to such lower price and additional shares of common stock will be issuable upon the conversion of the of the Series F Convertible Preferred Stock. To the extent the outstanding shares of Series F Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will experience further dilution.

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As of December 31, 2023, there were 11,950 shares of Series J Convertible Preferred Stock outstanding, convertible into 295,792 shares of common stock and 66,917 Series J Convertible Preferred Stock issuable upon the exercise of 133,834 warrants issued in the October 2023 Offering.

If any security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock could depress the trading market for our common stock over an extended period of time. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2023, we have outstanding warrants to purchase an aggregate of approximately 2,963,192 shares of our common stock, and options to purchase an aggregate of approximately 110,916 shares of our common stock, which, if exercised, may further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market.

The rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of our outstanding preferred stock and stock that may be issued in the future.

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

Our board of directors has previously approved, pursuant to this authority, the issuance of preferred stock, and we have 127 shares of Series F Preferred Stock outstanding and 11,950 shares of Series J Convertible Preferred Stock outstanding as of December 31, 2023. Upon liquidation, dissolution or winding-up of the Company, holders of our Series F Preferred Stock and Series J Convertible Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of such preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, *pari passu* with all the holders of common stock.

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

There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock.

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

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

On December 9, 2022, we effected a 1-for-100 reverse split of our outstanding common stock. This reverse stock split did not change the par value of our common stock or the number of common or preferred shares authorized by our Certificate of Incorporation. Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of December 31, 2023 our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F Preferred Stock, 600,000 of which are designated Series J Convertible Redeemable Preferred Stock and we have 5,682,461 shares of

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common stock outstanding, 3,495,757 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, 66,917 Series J Convertible Preferred Stock issuable upon the exercise of 133,834 warrants issued in the October 2023 Offering, and 41,871 shares of common stock reserved for future grant under the Company's equity incentive plans.

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

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

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

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

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, 2022, we had U.S. net operating loss (“NOL”) carryforwards of approximately \$198.1 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 \$78.0 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, 2022, the Company no longer had tax loss carryforwards in the Commonwealth of Australia due to the dissolution of its Australian 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.

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

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

Further, our Certificate of Incorporation establishes that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

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 may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million.

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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.

RISKS RELATED TO OUR BUSINESS

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.

Prior to our acquisition of the Aquadex Business in August 2016, we did not have a product approved for commercial sale and focused our resources on developing and manufacturing our C-Pulse System. On September 29, 2016, we announced a strategic refocus of our strategy that included halting all clinical evaluations of the C-Pulse System to fully focus our resources on commercializing our Aquadex System, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives. In addition, our business strategy depends in part on our ability to grow our business by establishing an effective sales force and selling our products to hospitals and other healthcare facilities while controlling costs. In addition to heart failure, we have expanded our commercialization efforts into critical care and post-cardiac surgery. In February 2020, we received 510(k) clearance of the Aquadex SmartFlow system to include pediatric patients who weigh 20kg or more. With this 510(k) clearance, we have expanded our commercialization efforts into pediatrics. We have limited prior experience with respect to sales or marketing of the Aquadex System across heart failure, critical care, post-cardiac surgery and pediatrics. If we are unsuccessful at marketing and selling our Aquadex System, our operations and potential revenues will be materially adversely affected.

We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near-term.

We are an emerging company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of \$14.7 million as of September 30, 2023. As of September 30, 2023, our accumulated deficit was \$282.1 million.

Prior to August 2016, we did not have any products approved for commercialization, generated only limited revenue from our clinical studies and had significant operating losses as we incurred costs associated with the conduct of clinical studies and our research and development programs for our C-Pulse System. We became a revenue-generating company only after acquiring the Aquadex Business from a subsidiary of Baxter in August 2016. We expect to incur additional losses in the near-term as we grow the Aquadex Business, including investments in expanding our sales and marketing capabilities, manufacturing components, and complying with the requirements related to being a U.S. public company listed on Nasdaq. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require us to succeed in a range of challenging activities, including training personnel at hospitals and effectively and efficiently manufacturing, marketing and distributing the Aquadex System and related components. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

We believe that we will need to raise additional capital to fund our operations through the end of fiscal year 2024. If additional capital is not available, we will have to delay, reduce, or cease operations.

We believe that we will need to raise additional capital to fund our operations through the end of fiscal year 2024; however, there can be no assurance of this. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, the risk that we may not be able to continue as a going concern may make it more difficult to obtain necessary additional funding on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, require us to use our cash to make payments under such indebtedness, force us to maintain specified liquidity or other ratios or restrict our

ability to pay dividends or make acquisitions. If we are unable to secure additional funding, our development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations.

If we do not comply with certain tax regulations, including VAT, and similar regulations, we may be subject to additional taxes, customs duties, interest, and penalties in material amounts, which could materially harm our financial condition and operating results.

As a result of supplying our business customers in the European Union, we are subject to the Value Added Tax, or VAT, which is typically applied to all goods and services purchased and sold throughout Europe. In 2023, we discovered that our VAT returns from 2017 to 2021 were overdue for filing in Germany. While we do not believe our current exposure is material, we are unable to calculate any interest or penalties that may be assessed. Our tax advisors are working directly with the German tax authorities to determine the value of our exposure.

It is possible that we could face VAT audits in the future and that our liability for these taxes could exceed our estimates if non-U.S. tax authorities assert that we are obligated to collect additional tax amounts from our customers and remit those taxes to those authorities. Such an audit could be expensive and time-consuming and result in substantial management distraction. If the matter were to be resolved in a manner adverse to us, it could have a material adverse effect on our results of operations and financial condition. Additionally, we could be subject to interest and penalties for any assessment of taxes that could be deemed overdue.

Changes in or the improper application of VAT may negatively impact our operating results. Fluctuations in tax rates and duties, changes in tax legislation or regulation or adverse outcomes of these examinations could have a material adverse effect on our results of operations, financial condition, and cash flows.

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.

Our near-term prospects are highly dependent on revenues from a single product, the Aquadex System, and we have no other commercial products at this time. The established market or customer base for our Aquadex System is limited and our success depends on our ability to increase adoption and utilization of the Aquadex System. Acceptance of our product in the marketplace by health care providers is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform health care providers of the benefits of using the Aquadex System and to provide further training on its use. We may not be able to build key relationships with health care providers to drive further sales in the United States or sell the Aquadex System outside the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. In addition, market acceptance of the Aquadex System may require that we make enhancements to the system or its components. We cannot be sure that we will be able to successfully develop such enhancements, or that if developed they will be viewed favorably by the market. Our ability to achieve acceptance of our Aquadex System depends on our ability to demonstrate the safety, efficacy, ease-of-use and cost-effectiveness of the system. We may not be able to expand the adoption and market acceptance of the Aquadex System to both the inpatient and outpatient markets and our potential sales could be harmed.

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.

Our ten largest customers represented 55.4% and 53.3% of our revenues in the nine months ended September 30, 2023 and 2022, respectively, with our largest customer representing 16.9% and 13.3%, respectively, of our revenues during such periods. Customer ordering patterns may vary significantly from quarter to quarter, or customers may discontinue providing therapies using our products. If one of our largest customers reduced its purchases in a fiscal period, our revenues for that period may be materially adversely affected. Further, if one of our largest customers discontinued the use of our products, our revenues may be materially adversely affected.

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 have limited experience in commercial manufacturing of the Aquadex System. Following the acquisition of the Aquadex Business in 2016, we began manufacturing Aquadex FlexFlow® consoles and blood circuits in-house in the fourth quarter of 2017 and Aquadex FlexFlow® catheters in-house in the third quarter of 2018. We have manufactured the Aquadex SmartFlow® console since its development in 2019. However, because we have limited prior commercial manufacturing experience, we may incur manufacturing inefficiencies, delays, or interruptions. We may not be able to achieve low-cost manufacturing capabilities and processes that will enable us to manufacture the Aquadex System or related components in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design and production standards required to market our products successfully. If we experience difficulties with our manufacturing operations, we may experience delays in providing products and services to our customers, and our business could be harmed.

We depend upon third-party suppliers, including single-source suppliers, making us vulnerable to supply problems and price fluctuations.

We will rely on third-party suppliers, including single-source suppliers, to provide us with certain components of the Aquadex System. We have no long-term contracts with the majority of our third-party suppliers that guarantee volume or the continuation of payment terms. We depend on our suppliers to provide us with materials in a timely manner that meet our quality, quantity and cost requirements. The forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. If we do not increase our sales volumes, which drive our demand for our suppliers' products, we may not procure volumes sufficient to receive favorable pricing, which could impact our gross margins if we are unable to pass along price differences to our customers. Recent global economic cost inflation trends could unfavorably impact pricing from our suppliers, which could impact our gross margins if we are unable to pass along price differences to our customers. Our failure to obtain required components or subassemblies when needed and at a reasonable cost would adversely affect our business. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. Any difficulties in locating and hiring third-party suppliers, or in the ability of third-party suppliers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business.

The COVID-19 pandemic and other public health threats or outbreaks of communicable diseases could have a material adverse effect on our operations and overall financial performance.

Several hospitals in the U.S. included the Aquadex System in their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff are limited. However, we also experienced changes to our sales practices due to restrictions on hospital access and believe that such restrictions negatively affected revenue in other areas. As of the date of this prospectus, the extent to which the COVID-19 pandemic may continue to impact our financial condition or results of operations or guidance is uncertain and cannot be reasonably estimated but could be material and last for an extended period of time. The effect of the COVID-19 pandemic may not be fully reflected in our results of operations and overall financial performance until future periods.

The COVID-19 pandemic and accompanying market volatility, uncertainty and economic disruption also have the effect of heightening many of the other risks described herein.

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.

Our strategy requires us to provide a significant amount of customer service, maintenance, and other technical service to our customers. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure that we will be able to organize and manage this network on a cost-effective basis. If we cannot effectively organize and manage this network, then it may be difficult for us to distribute our products and to provide competitive service and support to our customers, in which case customers may be unable, or decide not, to order our products 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.

Competition from medical device companies and medical device divisions of health care companies, pharmaceutical companies and gene- and cell-based therapies is intense and expected to increase. The vast majority of patients with fluid overload receive pharmacological treatment (diuretics) as a standard of care. There are no direct competitors for the Aquadex System in heart failure or critical care in the U.S., other than diuretics. Other systems, such as Baxter's Prismaflex, a filter-based device that is approved for continuous renal replacement therapy for patients weighing 20kg or more with acute renal failure and/or fluid overload. In pediatrics, the Carpediem system distributed by Medtronic is indicated for use in acute kidney injury or fluid overloaded patients requiring hemodialysis or hemofiltration therapy, and Baxter's HF20 Set is authorized under an Emergency Use Authorization to deliver CRRT to treat patients of low weight (8-20 kg) in an acute care environment during the COVID-19 pandemic.

Our ability to compete effectively depends upon our ability to demonstrate the advantages of ultrafiltration as compared to diuretics, a pharmacological treatment that is currently the standard of care. In addition, we need to distinguish Aquadex System from the indirect competition of other devices that can also be used to conduct ultrafiltration.

Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales.

Our business strategy depends in part on our ability to expand the use of the Aquadex System in the market as quickly as possible. To achieve expanded market use of the Aquadex System, we may develop additional enhancements to the system or its components. Depending on their nature, such enhancements may be subject to review by the FDA and regulatory authorities outside of the United States under the applicable regulations. Any regulatory delay in our ability to implement enhancements to the Aquadex System or its components could have an adverse effect on our potential sales.

Health care laws in the United States and other countries are subject to ongoing changes, including changes to the amount of reimbursement for hospital services. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business may be enacted or promulgated, and the interpretation, application or enforcement of the existing laws and regulations may change. Legislative proposals can substantially change the way health care is financed by both governmental and private insurers and may negatively impact payment rates for our system. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcements or the specific effects any of these might have on our business. However, in the United States and international markets, we expect that both government and third-party payers will continue to attempt to contain or reduce the costs of health care by challenging the prices charged, or deny coverage, for health care products and services. Any future laws, regulations, interpretations, applications or enforcement could delay or prevent regulatory approval or clearance of our Aquadex System and our ability to market our Aquadex System. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA and/or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products.

In the United States, the products included in the Aquadex System are purchased primarily by customers, such as hospitals or other health care providers. Customers bill various third-party payers for covered therapies involving the Aquadex System provided to patients. These payers, which include federal health care programs (e.g., Medicare and Medicaid), state health care programs, private health insurance companies and managed care organizations, then reimburse our customers based on established payment formulas that consider part or all of the cost associated with these devices and the related procedures performed.

While the agency responsible for administering the Medicare program, the Centers for Medicare and Medicaid Services, has not issued a favorable national coverage determination under its Investigational Device Exception Studies Program for ultrafiltration using the Aquadex System, a number of private insurers have approved reimbursement for the products included in the Aquadex System for specific indications and points of service. In addition, patients and providers may seek insurance coverage on a case-by-case basis. On January 1, 2022, a new and dedicated Category III Current Procedural Terminology (CPT) code, 0692T, became effective for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver

ultrafiltration to adult and pediatric patients ($\geq 20\text{kg}$). The approved temporary Therapeutic Ultrafiltration Category III CPT code will be in effect for at least five years and provides additional reimbursement for ultrafiltration administered in the outpatient setting.

Product defects, resulting in lawsuits for product liability, could harm our business, results of operations and financial condition.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of a product or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to a product (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall of our Aquadex System or any related components could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

We may be held liable if any product we develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. The safety studies we must perform, and the regulatory approvals required to commercialize our products will not protect us from any such liability. We carry product liability insurance with a \$6.0 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any approved product. If such insurance is insufficient to protect us, our business, results of operations and financial condition will be harmed. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. Even if a product liability claim against us is without merit or if we are not found liable for any damages, a product liability claim could result in decreased interest in our registry studies, decreased demand for our system, if approved for commercialization, injury to our reputation, diversion of management's attention from operating our business, withdrawal of study participants, significant costs of related litigation, loss of revenue or the inability to commercialize our products.

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.

We market our products globally. Our international operations are subject to a number of risks, including the following: fluctuations in exchange rates of the United States dollar could adversely affect our results of operations, we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems, have our products serviced or conduct other operations, political instability could disrupt our operations, some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow, and some countries could impose additional taxes or restrict the import of our products. In addition, regulations in individual countries or regions may restrict our ability to sell our products. Most countries, including the countries in the EU, require approval or registration to import and/or sell our products in the country.

The EU Medical Device Regulation 2017/745 (MDR) was published in May 2017. There was a three-year transition period for companies to comply with the new MDR requirements, until May 2020. Due to the COVID, the date was extended to May 2021. To ensure a high level of public health protection and avoidance of device shortage, on March 20 2023, Regulation (EU) 2023/607 amended the MDR as regards the transitional provisions from May 26, 2024 further based on the different device classifications, provided certain criteria are met.

Our legacy devices, the Aquadex SmartFlow system, including the console and blood circuit, is considered non-implantable, class IIb device. The EU MDR transition period has been extended from May 26, 2024 to December 31, 2028. To qualify for the EU MDR transition extension, Nuwellis must

- apply for MDR certification with an MDR notified body by 26 May 2024 and before their MDD certificate expires, and
- have a contract in place with an MDR notified body before 26 September 2024.

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We are in the process of entering into MDR certification contract with our Notify Body which will allow Nuwellis to market Aquadex SmartFlow® through Dec 31st, 2028. Nuwellis intends to complete MDR certification and CE Mark under MDR prior to the extension deadline of Dec 31st, 2028.

If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the EU, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales will suffer.

Approval or clearance of our products could be withdrawn, delayed, or denied by the EU, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The EU imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure to comply with these requirements could prevent us from marketing our products in the European Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States. Our manufacturing facilities have not been inspected and certified by a worldwide testing and certification agency (also referred to as a notified body) that performs conformity assessments to EU requirements for medical devices. A “notified body” is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections. We cannot be sure that our facilities or the processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent obtaining the approvals we need to market our products in the European Community and the United States.

To market our products in the European Community, the United States and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our products, if we choose to subcontract manufacturing to a contract manufacturer, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers or we fail to address issues raised by the FDA in these inspections, then we may not be able to continue to market the products manufactured in such facilities and our revenues may be materially adversely affected.

If we violate any provisions of the FDC Act or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies.

We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our medically approved products.

If we violate the FDC Act or other regulatory requirements at any time during or after the product development and/or approval process, we could be subject to enforcement actions by the FDA or other agencies, including: fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of the production of our products, withdrawal of any existing approvals or pre-market clearances of our products, refusal to approve or clear new applications or notices relating to our products, recommendations that we not be allowed to enter into government contracts and criminal prosecution. Any of the above could have a material adverse effect on our business, financial condition and results of operations.

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 cannot assure you that our products will prove to be safe or that there will not be serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur significant expenses, limit our ability to market our products and generate revenues from such products or cause us reputational harm.

Under the FDC Act, we are required to submit medical device reports, or MDRs, to the FDA to report device-related deaths, serious injuries and malfunctions of medically approved products that could result in death

or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following: information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications; because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us.

If any of these events occur, then we could incur significant expenses and it could become more difficult for us to market and sell our products and to generate revenues from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our products.

We face significant uncertainty in the industry due to government healthcare reform.

The Affordable Care Act, as well as other healthcare reform may have a significant impact on our business. The Affordable Care Act is extremely complex, and, as a result, additional legislation is likely to be considered and enacted over time. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The uncertainties regarding the implementation of the Affordable Care Act, including possible repeal of the Affordable Care Act, ongoing legal challenges, and further judicial interpretations, create unpredictability for the health care industry, which itself constitutes a risk.

The Affordable Care Act includes a Hospital Readmission Reduction program and is designed to reduce payments to hospitals with excess heart failure readmissions, among other conditions. The penalty to hospitals can be significant, as much as 3% of total Medicare reimbursement. We believe the Aquadex System may offer hospitals an economic benefit for using the device on a regular basis for in-patient or out-patient usage to avoid readmissions for heart failure; however, if the Hospital Readmission Reduction program is repealed, hospitals may not be as inclined to take measures to reduce readmissions.

In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years, but if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future.

Moreover, the Physician Payment Sunshine Act (the “Sunshine Act”), which was enacted as part of the Affordable Care Act, requires applicable medical device companies to track and publicly report, with limited exceptions, all payments and other transfers of value to physicians and teaching hospitals in the U.S. Implementing regulations for these tracking and reporting obligations were finalized in 2013, and companies have been required to track payments made since August 1, 2013. If we fail to comply with the data collection and reporting obligations imposed by the Sunshine Act, we may be subject to substantial civil monetary penalties.

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.

Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the Stark law and federal False Claims Act (the “FCA”). These laws may impact, among other things, our sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors,

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prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. The physician self-referral laws, commonly referred to as the Stark law, is a strict liability statute that generally prohibits physicians from making referrals for the furnishing of any “designated health services,” for which payment may be made under the Medicare or Medicaid programs, to any entity with which the physician (or an immediate family member) has an ownership interest or compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self-referrals, regardless of the source of the payment for the patient’s care. If it is determined that any of the relationships we may have with physicians violate the Stark law or similar statutes, we could become subject to civil and criminal penalties. The imposition of any such penalties could harm our business.

The FCA prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the FCA, known as “qui tam” actions, can be brought by any individual on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a FCA action. When an entity is determined to have violated the federal FCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal FCA.

We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations.

Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws could subject us to penalties and other adverse consequences.

We are subject to the Foreign Corrupt Practices Act (“FCPA”), the U.K. Bribery Act and other anti-corruption, anti-bribery and anti-money laundering laws in various jurisdictions both domestic and abroad. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The U.K. Bribery Act is similar but even broader in scope in that it prohibits bribery of private (non-government) persons as well. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including its international subsidiary, and to devise and maintain an adequate system of internal accounting controls for international operations. Our distribution arrangements outside the U.S. presents some risk under these laws. Our distributors may sell our products to healthcare providers that are owned, controlled or managed by a foreign government and its employees, including healthcare providers that may be deemed to be a foreign official under the FCPA. We could be held liable for the actions of our distributors. While we have policies and procedures to address compliance with these laws, we cannot assure you that our distributors will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. Noncompliance with these laws could subject us to investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, adverse media coverage and other consequences. Any investigations, actions or sanctions could adversely affect our business, operating results and financial condition.

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 pursue acquisitions to obtain complementary businesses, products or technologies. Any such acquisition may not produce the revenues, earnings or business synergies that we anticipate, and an acquired

business, product or technology might not perform as we expect. Our management could spend a significant amount of time, effort and money in identifying, pursuing and completing the acquisition. If we complete an acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired businesses, products or technologies into our operations. In particular, we may lose the services of key employees and we may make changes in management that impair the acquired business's relationships with employees, vendors and customers. Additionally, we may acquire development-stage companies that are not yet profitable and which require continued investment, which could decrease our future earnings or increase our future losses.

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced.

As a result of a potential acquisition, we may be required to capitalize a significant amount of intangibles, including goodwill. We would be required review our definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets. In addition, we would be required to evaluate goodwill for impairment annually, or to the extent events or conditions indicate a risk of possible impairment during the interim periods prior to its annual impairment test. In the year ended December 31, 2017, we recognized impairment charges of \$4.0 million related to goodwill and intangibles assets from our acquisition of the Aquadex Business. If we were required to recognize impairment charges related to future acquisitions, those charges could decrease our future earnings or increase our future losses.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our Aquadex System and related components. On August 5, 2016, upon closing of our acquisition of the Aquadex Business, we entered into a patent license agreement with Baxter pursuant to which we obtained, for no additional consideration, a world-wide license to 49 exclusively licensed and 9 non-exclusively licensed patents used in connection with the Aquadex System to make, have made, use, sell, offer for sale and import, the Aquadex System in the "field of use" as defined in the license. The license is exclusive, with respect to some patents, and non-exclusive, with respect to other patents. Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven "required maintenance patents," and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, or have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. We estimate that the patents licensed from Baxter will expire by mid-2026.

We have twenty pending patent applications. The first application is based on our design for a wearable device designed to assist in maintaining peripheral venous blood flow access in the arm during ultrafiltration treatment. The second application includes multiple potential new features and capabilities relating to help patient fluid balance and to improve usability for healthcare providers. The third application involves a vacuum pump-controlled wearable appliance to increase vein diameter and venous flow for peripheral ultrafiltration. The fourth application involves plasma and blood volume measurement to guide ultrafiltration therapy. The fifth application involves new features for ultrafiltration for the benefit of pediatric patients. The sixth application involves a dual-lumen ultrafiltration catheter for improved peripheral access. The seventh application involves a combination of diagnostic parameters to guide ultrafiltration therapy. The eighth application involves a multi-stage cytokine filtration system. The ninth application involves a system for ensuring that peripheral venous flow is maintained during ultrafiltration and other CKRT modalities. The tenth application enables an ultrafiltration system to provide better patient fluid balance.

In addition, as of January 30, 2024, we owned 16 issued patents and 14 pending patent applications in the United States and 6 in foreign jurisdictions related to our C-Pulse System and had one pending application for

neuromodulation. We estimate that most of our currently issued U.S. patents will expire by 2026. Given the strategic refocus away from the C-Pulse System and towards the Aquadex System, we have chosen to limit the maintenance of issued C-Pulse System related patents to those innovations that are of the highest value. Further, we have elected to emphasize a few of the most critical jurisdictions rather than maintain the earlier approach that involved multiple countries.

Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any financial return. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to obtain commercial benefits from them. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from our business.

Intellectual property litigation could be costly and disruptive to us.

In recent years, there has been significant litigation involving intellectual property rights in the medical device industry. From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in our business. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following, (i) halt us of our Aquadex System; (ii) attempt to obtain a license to sell or use the relevant technology, which license may not be available on reasonable terms or at all; or (iii) redesign our system

In the event a claim against us were successful and we could not obtain a license to the relevant technology on acceptable terms or license a substitute technology or redesign our system to avoid infringement, our business, results of operations and financial condition would be significantly harmed.

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.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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.

Our commercial success depends, in part, on our ability to increase adoption of the Aquadex System without infringing the patents and other proprietary rights of third parties. As our industry expands and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our system and technologies of which we are not aware or that we must challenge to continue our operations as currently contemplated. Our system may infringe or may be alleged to infringe these patents.

In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed, and may in the future file, patent applications covering our system or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application

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on inventions similar to ours, we may have to participate in an interference or derivation proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in our industry, we employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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.

In the ordinary course of our business, we may collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or others. At times we may have access to limited amounts of protected health information as part of other healthcare providers' provision of treatment to patients with our medical devices. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information, including: loss of access risk; inappropriate disclosure risk; inappropriate modification risk; and the risk of our being unable to adequately monitor our controls over the first three risks.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy. Although we take measures to protect sensitive information from unauthorized processing or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws and regulations that protect the privacy of personal information and regulatory penalties. To the extent that we may engage in activities regulated by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Clinical and Economic Health Act (HITECH) we may have additional regulatory and reporting obligations. We are also subject to the General Data Protection Regulation (EU) 2016/679 due to our business in the EU. Although we believe we have implemented security measures, there is no guarantee we can protect our systems and data from unauthorized access, loss or dissemination that could also disrupt our operations, including our ability to conduct our analyses, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

SPECIAL 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.

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

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$7.0 million (assuming the sale of all units offered hereby at the assumed public offering price of \$0.49 per unit, which represents the closing sale price of our common stock on the Nasdaq Capital Market on January 26, 2024), after deducting placement agent fees and estimated offering expenses payable by us, and assuming no sale of any pre-funded units offered hereunder. However, because this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, the actual offering amount, placement agent fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus, and we may not sell all or any of the securities we are offering. As a result, we may receive significantly less in net proceeds. Based on the assumed offering price set forth above, we estimate that our net proceeds from the sale of 75% or 50% of the units offered in this offering would be approximately \$5.1 million and \$3.3 million, respectively, after deducting placement agent fees and estimated offering expenses payable by us, and assuming no sale of any pre-funded units in this offering.

This estimate excludes the proceeds, if any, from the exercise of the common warrants sold in this offering. If all of the common warrants sold in the offering were sold and exercised for cash, we would receive additional net proceeds of approximately \$8.0 million. If 75% and 50% of the common warrants offered in this offering were sold and exercised for cash, we would receive additional net proceeds of approximately \$6.0 million and \$4.0 million, respectively. We cannot predict when or if these common warrants will be exercised. It is possible that these common warrants may expire and may never be exercised.

A \$0.05 increase or decrease in the assumed public offering price of \$0.49 per unit would increase or decrease the net proceeds from this offering by approximately \$0.8 million, assuming that the number of units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting placement agent fees and estimated offering expenses payable by us, and assuming no sale of any pre-funded units offered hereunder.

Similarly, a 4,081,632 unit increase or decrease in the number of units offered by us, as set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us by approximately \$1.8 million, assuming the assumed public offering price of \$0.49 per unit remains the same, and after deducting placement agent fees and estimated offering expenses payable by us, and assuming no sale of any pre-funded units offered hereunder.

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

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

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

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

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

CAPITALIZATION

The following table summarizes our unaudited capitalization as of September 30, 2023. Such information is set forth on the following basis (i) on an actual basis; (ii) pro forma basis, giving effect to the October 2023 Offering; and (iii) on a pro forma as adjusted basis, giving effect to the sale of the securities in this offering at the assumed public offering price of \$0.49 per unit, which represents the closing sale price of our common stock on the Nasdaq Capital Market on January 26, 2024, and an aggregate offering amount of \$8,000,000, and assuming no issuance of pre-funded units, after deducting placement agent fees and estimated offering expenses, and excluding the proceeds, if any, from the subsequent exercise of the common warrants issued pursuant to this offering.

You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operation,” as well as our financial statements and related notes and the other financial information, each as included in this prospectus. The information presented in the capitalization table below is unaudited.

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 September 30, 2023 (in thousands, except share and per share data)		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	\$ 4,930	\$ 6,412	13,401
Stockholders’ equity:			
Series A junior participating preferred stock, par value \$0.0001 per share; authorized 30,000 shares, none outstanding actual, pro forma and pro forma as adjusted	—	—	—
Series F convertible preferred stock, par value \$0.0001 per share; authorized 18,000 shares, issued and outstanding 127 shares actual, pro forma and pro forma as adjusted	—	—	—
Series J convertible preferred stock, par value \$0.0001 per share; authorized 600,000 shares, issued and outstanding 0, 150,000 and 150,000 shares, actual, pro forma and pro forma as adjusted, respectively	—	—	—
Common stock, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 1,864,265, 1,864,265 and 18,190,795 shares actual, pro forma and pro forma as adjusted, respectively	—	—	2
Additional paid-in capital	289,980	291,462	298,449
Accumulated other comprehensive income:			
Foreign currency translation adjustment	(24)	(24)	(24)
Unrealized gain on marketable securities	—	—	
Accumulated deficit	(282,117)	(282,117)	(282,117)
Total stockholders’ equity	7,839	9,321	16,310

A decrease in the number of units offered by us to 12,244,898 units (resulting in gross proceeds of approximately \$6.0 million) would decrease cash, decrease total stockholders’ equity, and decrease total capitalization on a pro forma as adjusted basis by approximately \$1.8 million from the amounts presented in the table above, assuming the assumed offering price of \$0.49 per unit remains the same, and after deducting placement agent fees and commissions and estimated offering expenses payable by us. The Company has not completed its review of the accounting treatment and fair value of the common warrants and pre-funded warrants offered hereby. The table above assumes the common warrants and pre-funded warrants are accounted for within equity. If the Company determines the warrants are to be accounted for as liabilities, the fair value of the warrants will be recognized as a liability and subsequently recorded at fair value each reporting period with the change in fair value recognized within income.

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The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. The pro forma column reflects our registered public offering in October 2023 and the pro forma as adjusted column reflects our sale of units in this offering at an assumed offering price of \$0.49 per unit, assuming no sale of any pre-funded units offered hereunder. The number of shares of our common stock to be outstanding after this offering is based on 1,864,265 shares of common stock outstanding as of September 30, 2023, gives effect to the October 2023 Offering, and excludes as of such date:

- 111,275 shares of our common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of \$36.78 per share;
- 1,308,271 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 \$35.51 per share;
- 5,080 shares of our common stock issuable upon the conversion of the 127 outstanding shares of our Series F Preferred Stock;
- 3,712,871 shares of our common stock issuable upon the conversion of the 150,000 outstanding shares of our Series J Convertible Preferred Stock;
- 1,856,435 shares of common stock issuable upon the conversion of 75,000 Series J Convertible Preferred Stock issuable upon the exercise of the 150,000 warrants issued in the October 2023 Offering; and
- 49,456 shares of our common stock reserved for future issuance under our equity incentive plans.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim condensed consolidated financial statements and related notes and our audited consolidated financial statements and related notes included elsewhere in this prospectus.

Overview

About Nuwellis

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

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

Impact of COVID-19 Pandemic

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

Recent Developments

Nasdaq Notice

On December 7, 2023, we received a letter (the "Notice") from The Nasdaq Stock Market ("Nasdaq") advising that for 30 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the \$1.00 per share minimum required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Notice has no effect on the listing of our common stock at this time, and our common stock continues to trade on the Nasdaq Capital Market under the symbol "CHFS." Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice (the "Compliance Period"), the closing bid price of our common stock is at or above \$1.00 for a minimum of 10 consecutive business days, we will regain compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq Capital Market, absent noncompliance with any other requirement for continued listing. If we do not regain compliance with the Minimum Bid Price Requirement by the end of the Compliance Period (or the Compliance Period as may be extended) the Company's common stock will be subject to delisting. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement under the Nasdaq Listing Rules.

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Public Offering: On October 17, 2023, the Company closed on a public offering of 150,000 units (the “October 2023 Units”), with each October 2023 Unit consisting of one share of the Company’s Series J Convertible Redeemable Preferred Stock, par value \$0.0001 per share, with a liquidation preference of \$25.00 per share (the “Series J Convertible Preferred Stock”), and one warrant (the “October 2023 Warrants”) to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock.

The purchase price for one October 2023 Unit was \$15.00, which reflects the issuance of the Series J Convertible Preferred Stock with an original issue discount. The Series J Convertible Preferred Stock has a term of three (3) years and is convertible at the option of the holder at any time into shares of the Company’s common stock at a conversion price of \$1.01. If any shares of our Series J Convertible Preferred Stock are outstanding at the end of the three-year term, then the Company will promptly redeem all of such outstanding shares of Series J Convertible Preferred Stock on a *pro rata* basis among all of the holders of Series J Convertible Preferred Stock commencing on the third-year anniversary of the closing date of this offering (the “Mandatory Redemption Date”) in cash, to the extent legally permissible under Delaware law, or, if redemption for cash is not legally permissible in duly authorized, validly issued, fully paid and non-assessable shares of the Company’s common stock equal in number to the quotient obtained by dividing such unpaid amount by the closing price of the Company’s common stock on the Nasdaq on the Mandatory Redemption Date.

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

The October 2023 Warrants have a term of three (3) years. Each October 2023 Warrant has an exercise price of \$7.50 (50.0% of the public offering price per October 2023 Unit) per one-half of one share (0.5) of Series J Convertible Preferred Stock and is immediately exercisable.

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We have adopted various accounting policies to prepare the condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). Our most significant accounting policies are disclosed in Note 1 to the consolidated financial statements for the year ended December 31, 2022 included in this prospectus.

The preparation of the condensed consolidated financial statements, in conformity with U.S. GAAP, requires us to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to stock-based compensation, valuation of equity and debt securities, and income tax reserves are updated as appropriate, which in most cases is quarterly. We base our estimates on historical experience, valuations, or various assumptions that are believed to be reasonable under the circumstances. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management’s Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report on Form 10-K for the year ended December 31, 2022, which is incorporated by reference into this prospectus.

Revenue Recognition: We recognize revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers. Accordingly, we recognize revenue when our customers obtain control of their products or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods and services. See Note 2 – Revenue Recognition, included in our Financial Statements for the quarter ended September 30, 2023, which are included in this prospectus.

Accounts Receivable: Our accounts receivables generally have terms that require payment within 30 days. We did not establish an allowance for doubtful accounts as of September 30, 2023, as we have not incurred any write-offs or experienced a deterioration in the aging of our receivables, and we do not expect to experience write-offs in the future.

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

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

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

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

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

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

Loss per Share: Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. See Note 3 – Stockholders' Equity included in our condensed consolidated financial statements for the quarter ended September 30, 2023, which are included in this prospectus.

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

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

The Company continues to report operating losses and negative cash flows from operations, both of which it considers to be indicators of potential impairment. Therefore, the Company evaluates its long-lived assets for potential impairment at each reporting period. The Company has concluded that its cash flows from the various long-lived assets are highly interrelated and, as a result, the Company consists of a single asset group. As the Company expects to continue incurring losses in the foreseeable future, the undiscounted cash flow step was bypassed, and the Company

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proceeded to measure fair value of the asset group. The Company has determined the fair value of the asset group associated with its loaner units by using expected cash flows estimating future discounted cash flows expected from the rental of these units. For recently acquired assets within the asset group, primarily equipment, the Company determined the fair value based on the replacement cost. There have been no impairment losses recognized for the nine months ended September 30, 2023 or the year ended December 31, 2022.

Going Concern: Our consolidated financial statements have been prepared and presented on a basis assuming we continue as a going concern. During the years ended December 31, 2022 and 2021, and through September 30, 2023, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. As of September 30, 2023, we had an accumulated deficit of \$282.1 million, and we expect to incur losses for the foreseeable future. To date, we have been funded by debt and equity financings, and although we believe that we will be able to successfully fund our operations into the future, there can be no assurance that we will be able to do so or that we will ever operate profitably. These factors raise substantial doubt about the Company's ability to continue as a going concern through at least twelve months from the report date.

We became a revenue-generating company after acquiring the Aquadex Business in August 2016. We expect to incur additional losses in the near-term as we grow the Aquadex Business, including investments in our sales and marketing capabilities, product development, purchasing inventory and manufacturing components, generating additional clinical evidence supporting the efficacy of the Aquadex System, and complying with the requirements related to being a U.S. public company. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require us to succeed in training personnel at hospitals and effectively and efficiently manufacturing, marketing, and distributing the Aquadex System and related components. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability.

During 2022, we closed on an underwritten public offering for aggregate net proceeds of approximately \$9.4 million after deducting the underwriting discounts and commissions and offering expenses. See Note 4 – Stockholders' Equity, to the consolidated financial statements for the year ended December 31, 2022, which are included in this prospectus. The Company will require additional funding to grow its business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the issuance of equity securities or other financing transactions. Should future capital raising be unsuccessful, the Company may not be able to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

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

NEW ACCOUNTING PRONOUNCEMENTS

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

FINANCIAL OVERVIEW

We are a medical technology company focused on commercializing the Aquadex System for ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy. Activities since inception have consisted principally of raising capital, performing research and development, and conducting pre-clinical and

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clinical studies. During 2016, we acquired the Aquadex Business and announced that we were halting all clinical evaluations of our prior technology, the C-Pulse System. Since then, our activities have consisted mainly of expanding our sales and marketing capabilities, performing clinical research, and engaging in new product development. As of September 30, 2023, we had an accumulated deficit of \$282.1 million, and we expect to incur losses for the foreseeable future. To date, we have been funded by public and private equity financings and debt. Although we believe that we will be able to continue to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Comparison of three months ended September 30, 2023 to three months ended September 30, 2022

Net Sales

(in thousands)

Three months ended September 30, 2023	Three months ended September 30, 2022	Increase (Decrease)	% Change
\$2,412	\$2,065	\$347	16.8%

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with the Aquadex System consoles. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside of the United States to independent specialty distributors, who in turn sell to hospitals and clinics in their geographic regions. The increase in sales in the current year period is due to a 26% increase in circuit sales, reflecting continued increases in the number of patients treated with the Aquadex[®] therapy. By customer category, third quarter 2023 revenue in Heart Failure increased 27% over the same period last year, Critical Care and Pediatrics increased 16% and 9%, respectively.

Costs and Expenses

Our costs and expenses were as follows:

(in thousands)	Three months ended September 30, 2023	Three months ended September 30, 2022	Increase (Decrease)	% Change
Cost of goods sold	\$1,031	\$ 806	\$ 225	27.9%
Selling, general and administrative	\$3,428	\$4,251	\$(823)	(19.4)%
Research and development	\$1,117	\$ 928	\$ 189	20.4%

Cost of Goods Sold

The increase in cost of goods sold for the three months ended September 30, 2023, compared to the three months ended September 30, 2022, was due primarily to higher sales and lower manufacturing volumes causing lower fixed overhead absorption in the current year period.

Selling, General and Administrative

The decrease in selling, general and administrative expense primarily reflects decreased headcount and compensation related expenses incurred during the quarter.

Research and Development

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

Comparison of nine months ended September 30, 2023, to nine months ended September 30, 2022

Net Sales

(in thousands)

Nine months ended September 30, 2023	Nine months ended September 30, 2022	Increase (Decrease)	% Change
\$6,313	\$6,204	\$109	1.8%

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Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with the Aquadex system consoles. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside of the United States to independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. The increase in sales is primarily attributable to an increase in circuit sales and technical services partially offset by a decrease in console sales.

Costs and Expenses

Our costs and expenses were as follows:

<i>(in thousands)</i>	Nine months ended September 30, 2023	Nine months ended September 30, 2022	Increase (Decrease)	% Change
Cost of goods sold	\$ 2,718	\$ 2,780	\$(62)	(2.2)%
Selling, general and administrative	\$13,582	\$12,920	\$662	5.1%
Research and development	\$ 4,050	\$ 3,141	\$909	28.9%

Cost of Goods Sold

The decrease in cost of goods sold for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022, was primarily due to a one-time, non-cash inventory write-off of \$0.1 million in the prior-year period related to the discontinuation of a distribution agreement.

Selling, General and Administrative

The increase in selling, general and administrative expense primarily reflects increased professional fees related to consulting, marketing initiatives, and accounting and legal expenses associated with the Company's year-end audit, 2023 At-the-Market Offering, and the DaVita Supply Agreement.

Research and Development

The increase in R&D expense over the prior year was primarily driven by spending related to ongoing development of our pediatric continuous renal replacement therapy device.

Liquidity and Capital Resources

Sources of Liquidity

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

On October 18, 2022, the Company closed on an underwritten public offering of 209,940 shares of common stock and 23,157,124 shares of Series I convertible preferred stock, for gross proceeds of approximately \$11.0 million (the "October 2022 Offering"). Net proceeds totaled approximately \$9.4 million after deducting underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters' full exercise of their over-allotment option.

During the three months and nine months ended September 30, 2023, the Company issued none and 657,333 shares of common stock under the At-the-Market Program for gross proceeds of none and approximately \$2.3 million, respectively. Net proceeds for the three and nine months ended September 30, 2023, totaled none and approximately \$2.1 million, respectively, after deducting the underwriting discounts and commissions and other costs associated with the offering.

On October 17, 2023, the Company closed on a public offering of 150,000 Units, with each Unit consisting of one share of the Company's Series J Convertible Redeemable Preferred Stock, par value \$0.0001 per share, with a liquidation preference of \$25.00 per share (the "Series J Convertible Preferred Stock"), and one October 2023 Warrant to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock.

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

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

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

The October 2023 Warrants have a term of three (3) years. Each October 2023 Warrant has an exercise price of \$7.50 (50.0% of the public offering price per Unit) per one-half of one share (0.5) of Series J Convertible Preferred Stock and is immediately exercisable.

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

As of September 30, 2023 and December 31, 2022, cash and cash equivalents were \$4.9 million and \$17.7 million, respectively. Our business strategy and ability to fund our operations in the future depend in part on our ability to grow the Aquadex Business by expanding our salesforce, selling our products to hospitals and other healthcare facilities, and controlling costs. We will need to seek additional financing in the future, which, to date, has been primarily through offerings of our equity securities.

Cash Flows used in Operating Activities

Net cash used in operating activities was \$15.2 million and \$12.0 million for the nine months ended September 30, 2023, and September 30, 2022, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, partially offset by non-cash charges for stock-based compensation, depreciation and amortization, and revaluation of the warrant liability (in the current year period), and the effects of changes in operating assets and liabilities, including working capital.

Cash Flows provided by (used in) Investing Activities

Net cash provided by and used in investing activities was \$294,000 and (\$103,000) for the nine months ended September 30, 2023, and 2022, respectively. The cash provided by investing activities was from the sale of marketable securities and the cash used in investing activities was for legal costs related to new patent applications and for the purchase of manufacturing, laboratory, and office equipment, respectively, in those periods.

Cash Flows provided by (used in) Financing Activities

Net cash provided by and used in financing activities was \$2.1 million and (\$28,000) for the nine months ended September 30, 2023, and 2022, respectively. The cash provided by financing activities in the current year period was the result of proceeds received from the Company's 2023 At-the-Market Program, net of financing costs. The use of cash in the prior year period related to lease payment expense.

Capital Resource Requirements

As of September 30, 2023, we did not have any material commitments for capital expenditures.

Overview

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

Fluid Overload

Fluid overload, also known as hypervolemia, is a condition in which there is too much fluid in the blood, vital organs, and interstitial space, 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.⁹²

The signs and symptoms of fluid overload are not always the same in each patient and may vary. However, possible signs and symptoms of fluid overload include pulmonary edema/pleural effusion, peripheral edema, anasarca (swelling of the skin) ascites, jugular vein distention and dyspnea. Medical conditions or diseases where excess fluid accumulates in the body are heart failure, kidney failure, nephrotic syndrome, cirrhosis, or burn injuries/trauma. Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery, although fluid overload is the leading cause of death for critically ill patients in the ICU within 90 days of admission.⁹³ The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight, presence of pulmonary rales, and edema), blood chemistry, natriuretic peptides, liver enzymes, hemoglobin and hematocrit, blood volume analysis, and/or bioimpedance.⁹⁴ Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema⁹⁵ and is a leading cause of hospital readmissions with patients suffering from heart failure and patients following cardiac surgery.⁹⁶ Fluid overload is an independent risk factor for acute kidney injury in critical care patients.⁹⁵

The condition of fluid overload is often observed in patients with heart failure and secondary oliguric states,⁹⁸ although in pediatric patients, fluid overload is associated with significant increases in mortality.^{99, 100} Congestion or fluid overload, the hallmark of decompensated HF, is the primary reason for hospitalization in 90% of these patients.^{101, 102} For this reason, diuretics have been the cornerstone of heart failure treatment for more than 50 years.¹⁰³ Over the past 20 years, approaches to treatment have changed dramatically.¹⁰⁴ These dramatic improvements include new medications and new technologies, such as ultrafiltration, to help treat fluid overload. Each year there are over 1 million heart failure hospitalizations in the United States, and 90% of those hospitalizations are due to symptoms of

⁹² Murugan R et al. *Nature Rev Nephrol.* 2020; 1-14.

⁹³ Vaara ST et al. *Crit Care.* 2012; 16: 1-11.

⁹⁴ Koratala A et al. *Cardiorenal Med.* 2022;12(4):141-154.

⁹⁵ Stein, A, et. al. *Critical Care*; 2012;16:R99.

⁹⁶ Iribarne A, et al. *Ann Thorac Surg.* 2014; 98(4): 1274-80.

⁹⁷ Salahuddin N et al. *BMC Nephro.* 2022;18(1):1-8.

⁹⁸ Ronco C, et al. (2010) *Fluid Overload Diagnosis and Management.* Basel, Switzerland: Karger.

⁹⁹ Sutherland SM, et al. *Am J Kidney Disease.* 2010; 5(2): 316-25.

¹⁰⁰ Gillespie RS, et al. *Ped Nephro.* 2004; 19(12): 1394-99.

¹⁰¹ Kazory A & Costanzo MR. *Adv Chronic Kidney Dis.* 2018; 25(5): 434-442.

¹⁰² Fonarow GC. *Rev Cardiovasc Med.* 2003; 4: s21-30.

¹⁰³ Kamath, SA. *Int J of Nephrol.* 2011; 1-6.

¹⁰⁴ Ellison DH. *Cardiol.* 2001;96:132-143

fluid overload.¹⁰⁵ These patients are hospitalized on average for 8.3 days at a cost of approximately \$24,000¹⁰⁶, to which reimbursement will only cover about 34%¹⁰⁷ of that cost. On top of that, there is a 30-DAY readmission rate penalty for which the hospitals absorb another cost but do not get reimbursed with some data suggesting such penalties can cost a hospital up to \$15.2 million annually.^{108, 109, 110}

Treatments for Fluid Overload

Diuretics

Treatment for fluid overload has traditionally been achieved through use of oral or loop diuretics which may be accompanied by use of other categories of medications, such as ACE inhibitors, beta-blockers, and inotropic drugs. Chronic diuretic use has been associated with increased long-term mortality and hospitalizations in a wide spectrum of chronic systolic and diastolic HF patients.¹¹¹ Increasing concern exists that diuretics, particularly at high doses, may be deleterious in the inpatient setting. Diuretics have a variable dose response rate and studies have shown nearly 70% of heart failure patients treated with diuretics have a suboptimal response.^{112, 113} Additionally, between 10-40% of heart failure and cardiac surgery patients are refractory to diuretics,¹¹⁴ with diuretic resistance associated with a higher risk of in-hospital worsening of heart failure, increase mortality after discharge, and a 3-fold increase in rehospitalization rates.¹¹⁵ In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.¹¹⁶ Also, long term use of diuretics has been associated with kidney damage.¹¹⁷ Approximately 40% of heart failure patients have poor diuretic response.¹¹⁸ 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.¹¹⁹ Despite treatment with loop diuretics, patients are frequently hospitalized and treated for recurrent symptoms and signs of fluid overload. Among more than 50,000 patients enrolled in the Acute Decompensated Heart Failure National Registry (“ADHERE”) study, only 33% lost \geq 2.27 kg. (5 lbs.), and 16% gained weight during hospitalization.¹²⁰

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.¹²¹ Additionally, one study found that 24% of such patients were readmitted to the hospital within 30 days of their discharge, and 50% were readmitted within 90 days.^{122, 123} 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.¹²⁴ There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.¹²⁵ Therefore, an alternative therapy to help stabilize or improve patient care is needed.

¹⁰⁵ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-2445.

¹⁰⁶ From Premier Applied Sciences database.

¹⁰⁷ Reimbursement estimates from MCRA.

¹⁰⁸ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-2445.

¹⁰⁹ McIlvennan CK, et al. *Circ.* 2015;131(20):1796-803.

¹¹⁰ From Premier Applied Sciences database.

¹¹¹ Ahmed A, et al. *Eur Heart J.* 2006;27(12):1431-9.

¹¹² Kazory A & Costanzo MR. *Adv Chronic Kidney Dis.* 2018; 25(5): 434-442; 30.

¹¹³ Testani JM, et al. *Circ Heart Fail.* 2016; 9(1): e002370.

¹¹⁴ Testani JM, et al. *Circ Heart Fail.* 2016; 9(1): e002370.

¹¹⁵ Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-2445.

¹¹⁶ Kamath SA. *Int J of Nephrol.* 2011:1-6.

¹¹⁷ Felker MG & Mentz RJ. *J Am Coll Cardiol.* 2012;59(24):2145-53.

¹¹⁸ Testani JM, et al. *Circ Heart Fail.* 2016;9(1):e002370.

¹¹⁹ Hoorn EJ & Ellison DH. *Am J Kidney Dis.* 2017;69(1):136-142.

¹²⁰ Gheorghade M, et al. *Eur Heart J Suppl.* 2005; 7:B13-19.

¹²¹ Orso D, et al. *Eur Rev Med Pharmacol Sci.* 2021;25(7):2971-2980.

¹²² Costanzo MR, et al. *J Am Coll Cardiol.* 2017;69(19):2428-2445.

¹²³ Thandra A, et al. *Clin Invest.* 2023; 356(2): 145-51.

¹²⁴ Felker GM, et al. *N Engl J Med.* 2011; 364:797-805.

¹²⁵ Costanzo MR, et al. *J Am Coll Cardiol.* 2007; 49(6):675-683.

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 20 years.¹²⁶ Ultrafiltration is a safe and effective therapy to treat fluid overload and congestion by removing extra fluid overload and congestion by removing extra fluid and salt.¹²⁷ With ultrafiltration, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The use of ultrafiltration therapy in subgroups of patients, such as heart failure and post-cardiac surgery, has demonstrated clinical benefits in treating fluid overload signs and symptoms. 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.¹²⁸

The Aquadex System

The Aquadex System is designed and clinically proven to simply, safely, and precisely remove excess isotonic fluid (primarily excess salt and water) from patients suffering from fluid overload who have failed diuretic therapy.

With the Aquadex System, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The Aquadex System has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate.^{129, 130} 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. The company estimates it has treated nearly 26,000 patients across all three (3) of our customer categories, since it reintroduced the Aquadex System in the U.S. market in 2016.

Benefits of the Aquadex System

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

- Reduces hospitalization by 81%¹³¹ compared to diuretics;
- Rehospitalizations with Aquadex were 48% lower than the national average at 30 days;¹³²
- Reduces length of hospital stay when initiated early, resulting in average savings of \$3,975 (14%);¹³³
- Stabilizes or improves cardiac hemodynamics;^{134, 135}
- Safe, easy-to-use, and flexible in application;
- Provides complete 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;
- Can be performed via peripheral or central venous access;
- Predictably removes excess isotonic fluid (extracts water and sodium while sparing potassium and magnesium; decrease risk of electrolyte abnormalities);^{136, 137}
- No significant changes to kidney function;¹³⁸

¹²⁶ Agostoni PG, et al. *J Am Coll Cardiol.* 1993; 21(2):424-431.

¹²⁷ Kazory A, et al. *Cardiorenal Med.* 2023;13(1)1-8.

¹²⁸ Costanza MR, et al. *Value Health.* 2018; 21 (Suppl 1):S167.

¹²⁹ SAFE Trial: Jaski BE, et al. *J Card Fail.* 2003; 9(3): 227-231; RAPID Trial.

¹³⁰ Bart BA, et al. *J Am Coll Cardiol.* 2005; 46(11): 2043-2046.

¹³¹ Watson R et al. *J Cardiac Fail.* 2020; 26(10): s56.

¹³² Watson R et al. *J Cardiac Fail.* 2020; 26(10): s56.

¹³³ Costanza MR, et al. *Value Health.* 2018; 21 (Suppl 1):S167.

¹³⁴ Boga M, et al. *Perf.* 2000; ;15:143-150.

¹³⁵ Kiziltepe U, et al. *Ann Thorac Surg* 2001;71:684-93.

¹³⁶ Kazory A, et al. *Cardiorenal Med.* 2023;13(1)1-8.

¹³⁷ Agostoni PG et al. *J Am Coll Cardiol.* 1993;21(2):424-31.

¹³⁸ Kazory A, et al. *Cardiorenal Med.* 2023;13(1)1-8.

- The use of continuous hematocrit monitoring and SvO₂ sensor provides guided-therapy ultrafiltration.¹³⁹
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored.¹⁴⁰
- Provides highly automated operation with only one setting required to begin therapy;
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up; and
- Has a built-in console that guides the medical practitioner through the setup and operational process.

Components of the Aquadex System

The Aquadex System consists of:

- A console, a piece of capital equipment containing electromechanical pumps, an LCD screen and stand;
- A one-time disposable blood circuit set, 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, 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.

Our Market Opportunity

The Aquadex System is indicated for the treatment of patients suffering from fluid overload who have failed medical therapy including diuretics, or patients that can benefit from a predictable mechanical way to remove excess fluid (isotonic fluid). We are currently focusing our commercial activities in three primary clinical areas where fluid overload is prevalent: heart failure, critical care and pediatrics.

Heart Failure

Heart disease is the leading cause of death in the United States and other developed countries. In fact, approximately 50% of patients who develop heart failure die within five years of diagnosis. The five-year mortality rate for heart failure, regardless of heart function, is approximately 75% across all phenotypes.¹⁴¹ Approximately 6.7 million Americans over 20 years of age have heart failure, and the prevalence is expected to rise to 8.5 million Americans by 2030.¹⁴² Based on the Atherosclerosis Risk in Communities Study from 2005 to 2013, conducted by the National Heart, Lung and Blood Institute, there are an estimated 960,000 new heart failure cases annually.¹⁴³ Annual hospitalizations for heart failure exceed one million in both the United States and Europe, and more than 90% are due to symptoms and signs of fluid overload.¹⁴⁴ In addition, approximately 68% of patients are discharged with sub-optimal results.¹⁴⁵ As such, there are over 600,000 heart failure patients in the United States who might benefit from new technologies to treat fluid overload.

Heart failure is a syndrome that can have an acute onset or is a progressive disease caused by impairment of the heart's ability to pump blood to the various organs of the body. Patients with heart failure and fluid overload commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The heart becomes weak or stiff and enlarges over time, making it harder for the heart to pump the blood needed for the body to function properly. The severity of heart failure depends on how well a person's heart pumps blood throughout the body.¹⁴⁶

¹³⁹ Starr MC, et al. *Ped Nephro.* 2024;39(2):597-601.

¹⁴⁰ Costanzo MR, et al. *J Am Coll Cardiol.* 2005; 46(11): 2047-51.

¹⁴¹ Shah, K, et al. *J Am Coll Cardiol.* 2017 Nov, 70 (20) 2476–2486.

¹⁴² Bozhurt B, et al. *J Card Fail.* 2023; 29(10): 1412-42.

¹⁴³ Benjamin EJ, et al. *Circ.* 2017;135:00-00. (e378).

¹⁴⁴ Fonarow GC. *Rev Cardiovasc Med.* 2003; 4: s21-30.

¹⁴⁵ Testani JM, et al. *Circ Heart Fail.* 2016; 9(1): e002370.

¹⁴⁶ Arrigo M et al. *Nat Rev Dis Primers.*2020;6(16):1-15.

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According to a nationwide study of over 140,000 patients suffering from acute decompensated heart failure, over 38% of patients discharged were still symptomatic and about half of the patients were discharged with less than five pounds lost.¹⁴⁷ This clinical evidence from the ADHERE registry shows patients are discharged too early, while still showing evidence of fluid overload.

As a result of not fully having their fluid imbalance properly addressed prior to discharge from the hospital, patients are frequently being readmitted, with 30-day readmissions of 24% and 6-month readmissions of 44%, while 80% of patients are admitted directly to the emergency department as the first point of care.^{148, 149}

Heart failure often requires inpatient treatment, and it carries a huge economic burden in the United States, costing the nation an estimated \$60.2 billion each year, with hospital costs accounting for 62% of the economic burden.¹⁵⁰ As the population ages, healthcare expenditures are expected to increase substantially.¹⁵¹ Therefore, therapies aimed at treating congestion and fluid overload are essential from a patient care and healthcare economics perspective.

To remove the excess fluid, patients suffering from heart failure may receive ultrafiltration therapy in two settings: (i) *inpatient care*: provided to a patient admitted to a hospital, extended care facility, nursing home or other longer-term care facility; and (ii) *outpatient care*: provided to a patient who is not admitted to a facility, but receives treatment at a doctor's office, clinic, or hospital outpatient department.

Hospitals in the United States also face potential penalties for heart failure readmissions. As part of the Patient Protection and Affordable Care Act of 2012, as amended (the "Affordable Care Act"), Medicare instituted the Hospital Readmissions Reduction Program (HRRP), which penalizes hospitals with high 30-day readmission rates for heart failure and other common diseases and procedures. This penalty can be as high as 3% of reimbursement for all Medicare admissions. Technologies that help reduce readmissions, such as the Aquadex System, can help hospitals mitigate these penalties.¹⁵²

The Company believes the total U.S. heart failure market is approximately \$1 billion¹⁵³ and that roughly 30% of its revenue is derived from the treatment of heart failures patients.

Critical Care

Patients suffer from fluid overload in connection with a variety of critical care procedures and treatments, including cardiac surgery, cardiogenic shock, liver and other organ transplants, ventricular assist device ("VAD") implants, extra corporeal membrane oxygenation ("ECMO") therapy, sepsis, liver disease and severe burns. According to the National Center for Health Sciences, over 7.3 million cardiovascular operations are performed each year in the United States, including an estimated 340,000 coronary-artery bypass grafting (CABG) procedures,¹⁵⁴ 180,000 valve procedures,¹⁵⁵ and 3,000 VAD implants.¹⁵⁶ Cardiac surgery is associated with a degree of fluid overload due to cardiopulmonary bypass.¹⁵⁷ Intravenous fluid therapy is an integral treatment for patients undergoing surgery and in critical care units.¹⁵⁸ Fluid overload in post-cardiac surgery can readily occur because surgery can affect the pumping actions of the heart, leading to postoperative hemodynamic instability.¹⁵⁹ The condition often remains symptomless for several days until clinical symptoms become apparent, when treatment is almost always too late and ineffective.¹⁶⁰

¹⁴⁷ Fonarow et al. *Rev Cardiovasc Med*. 2003;4: Suppl 7:S21-30.

¹⁴⁸ Costanzo MR, et al. *J Am Coll Cardiol*. 2017;69(19):2428-2445.

¹⁴⁹ Sax D, et al. *J Card Fail*. 2022; 28(10): 1545-59.

¹⁵⁰ Voigt J, et al. *Clin Cardiol*. 2014;37(5): 312-321.

¹⁵¹ Heidenreich PA, et al. *Circ Heart Fail*. 2013;6(3):606-619.

¹⁵² McIlvennan C et al. *Circ*. 2015;131(20):1796-1803.

¹⁵³ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

¹⁵⁴ <https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/>.

¹⁵⁵ <https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/>.

¹⁵⁶ Kruger A et al. *J Cardiovasc Dev Dis*. 2023;10(6):263-78.

¹⁵⁷ Bowdish ME, et al. *Ann Thorac Surg*. 2021; 111(6): 1770-1780.

¹⁵⁸ Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.

¹⁵⁹ Xu J et al. *Med*. 2015. 94(33):e1360

¹⁶⁰ Xu J, et al. *Med*. 2015;94(33):e1360. 2017;103:32-40.

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The potential complications (e.g., renal failure, stroke, infection, arrhythmias, or prolonged intubation) are reported to be associated with high mortality, particularly when renal replacement therapy is required.¹⁶¹ Major complications after cardiac operations are associated with an increased risk for operative death, longer hospital length of stay, and higher rates of discharge to a location other than home.¹⁶² Hospital readmissions are a common problem in cardiac surgery and remain high. Approximately 20% of patients who undergo cardiac operations require readmission, an outcome with significant health economic implications. Volume overload was among the top three most prevalent causes for first readmission within 30 days and beyond 30 days.¹⁶³ It is estimated that 13.5% of post cardiac surgery patients are readmitted due to fluid overload within 30 days of discharge, which equates to an estimated 70,000 fluid overload-related readmissions for CABG, valve, and VAD procedures per year in the United States.¹⁶⁴ Positive research has been recently published demonstrating the value of ultrafiltration in high-risk coronary artery bypass grafting surgery.¹⁶⁵ It is also encouraging to see ultrafiltration being recommended for cardiac surgery patients who are unresponsive to diuretics in a recently published turnkey order set proposed by the ERAS Society consensus guidelines.¹⁶⁶

The Company believes it can expand use cases for the Aquadex System, without any additional clinical trial or other labeling changes at the FDA to support its use in the applications identified immediately above.

The Company believes the total U.S. critical care failure market is approximately \$900 million¹⁶⁷ and that approximately 40% of its revenue is derived from the treatment of critical care patients.

Pediatrics

Many of the conditions and procedures faced by adult patients also occur in pediatric patients, such as cardiac surgery, organ transplants, heart failure and ECMO therapy. Similar to adult patients, these conditions and procedures may lead to fluid overload. While incidence data is not readily available, it is estimated that there are approximately 10,000 to 14,000 pediatric patients with heart failure¹⁶⁸ and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation.^{169, 170, 171} Fluid overload drives pediatric morbidity and mortality risk in critically ill patients. In one pediatric study, a 3% increase in mortality was observed for every 1% increase in fluid overload, and children who are more than 20% fluid overloaded have an odds ratio for mortality of 8.5 compared to children who are less than 20% fluid overloaded.^{172, 173}

The Company believes that the total U.S. pediatric market for fluid overload is approximately \$130 million¹⁷⁴ and that roughly 30% of its revenue is derived from the treatment of pediatric patients.

While the Aquadex System is only FDA cleared for the treatment of pediatric patients weighing 20 kgs or more, the Company is aware that many children's hospitals in the U.S. are modifying the way that the Aquadex System is used in a manner that is deemed to be off-label by the Company and FDA in order to provide dialysis to neonates and other premature infants who weigh less than 20 kilograms and who were born either without kidneys or without normal kidney function. These patients typically have very few other treatment options given the large extracorporeal blood volume required by standard dialysis machines the need for blood priming of the dialysis circuit and the use of large catheters. By comparison, the Aquadex extracorporeal blood volume is only 35 milliliters. The Company estimates that when used on pediatric patients of any weight, clinicians use approximately 4 to 10 circuits per patient, and that the hospital typically owns or rents three-six consoles per hospital.

¹⁶¹ Granado RC et al. *BMC Nephro.* 2016;17:109-18.

¹⁶² Crawford TC, et al. *Ann Thorac Surg.* 2017;103:32-40.

¹⁶³ Iribane A, et al. *Ann Thorac Surg.* 2014;98:1274-80.

¹⁶⁴ Iribarne A, et al. *Ann Thorac Surg.* 2014; 98(4): 1274-80.

¹⁶⁵ Beckles DL et al. *J Card Surg.* 2022; 37: 2951-57.

¹⁶⁶ Engelman D, et al. *Ann Thorac Surg.* 2023;115:11-5A

¹⁶⁷ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

¹⁶⁸ Jayaprasad, N. *Heart Views.* 2016; 17(3): 92-99.

¹⁶⁹ <https://www.cdc.gov/ncbddd/heartdefects/data.html>.

¹⁷⁰ Karamlou T, et al. *J Thorac Cardiovasc Surg.* 2013 Feb;145(2):470-5.

¹⁷¹ <https://www.organdonor.gov/about/donors/child-infant.html>.

¹⁷² Sutherland SM, et al. *Am J Kidney Dis.* 2010;55(2).

¹⁷³ Gillespie RS, et al. *Ped Nephrol.* 2004;19(12): 1394-99.

¹⁷⁴ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

It is because of this unmet medical need the Company has undertaken the development of a dedicated CRRT device intended for patients weighing between 2.5 and 10 kilograms. See – Product Development Activities below.

Growing Clinical Evidence

In December 2021, we launched the REVERSE-HF prospective, multicenter, randomized controlled trial (RCT) to evaluate ultrafiltration compared to IV diuretics in patients with heart failure. This RCT is currently being conducted at sixteen clinical sites nationwide, and patient enrollment began in June 2022. As of December 31, 2023, there are 80 patients enrolled in this RCT. The primary effectiveness endpoint is the time to first Heart Failure (HF) Event within 30 days, as a comparison between Aquadex therapy and IV Loop Diuretics. The Company intends to target a total of 20 sites and hopes to be fully enrolled by the end of 2024 with a total of 372 patients enrolled. The protocol for REVERSE-HF permits an interim data analysis once enrollment reaches 80% of its targeted enrollment, and the Company hopes to complete analysis and to publish the results of the study in the second half of 2025.

Secondary endpoints will be analyzed as a comparison between Aquadex and IV Loop Diuretics:

- Composite win ratio analysis of Cardiovascular (CV) mortality, HF events, and quality of life within 30 days:
 - CV mortality
 - HF event
 - Change in Kansas City Cardiomyopathy Questionnaire (KCCQ) score
- Time to first HF event within 90 days
- Time to first HF event or all-cause death within 90 days
- HF events within 30 and 90 days
- Treatment crossovers

In December 2022, a third-party, real-world retrospective study of 335 patients treated with the Aquadex FlexFlow® System, “*Ten Year Experience with Ultrafiltration for the Management of Acute Decompensated Heart Failure*,”¹⁷⁵ compared previous randomized controlled clinical trials with ultrafiltration and demonstrated that ultrafiltration compares favorably in reducing heart failure rehospitalizations, renal function response, and weight/volume loss. The study found ultrafiltration to be safe with regard to renal function despite the cohort in this study being sicker than those studied in other clinical trials, and that Ultrafiltration can be a safe and effective strategy for decongestion in clinical practice wherein the benefits outweigh the potential risks of kidney dysfunction requiring hemodialysis and major bleeding events.¹⁷⁶ Additionally, another 2022 peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients.¹⁷⁷ Kazory et al. reviewed pooled data from seven randomized controlled trials of ultrafiltration with a total of 771 patients and concluded that extracorporeal ultrafiltration is associated with more efficient fluid and sodium removal compared with medical therapy, hence leading to a reduction in readmission rates and a potential salutary impact on financial burden associated with the care of heart failure patients.¹⁷⁸ Compared to diuretics, ultrafiltration provided predictable, adjustable, and more efficient fluid removal – without clinically adverse impacts on renal function, demonstrating a 14% cost reduction at 90-days achieved due to reduced readmissions.¹⁷⁹

The AVOID-HF trial was initiated by Baxter in 2016. AVOID-HF was designed to prospectively address the question of patient outcomes when treated with ultrafiltration versus intravenous diuretics for acute decompensated heart failure. Trial design assumptions indicated that 810 patients would need to be randomized to achieve adequate statistical power. However, the study was terminated by Baxter at 224 patients, apparently for business reasons unrelated to patient outcomes or device safety. Despite being underpowered, the results of

¹⁷⁵ Watson R et al. *Am Heart J Plus: Cardiol Res & Pract* 24,2022;1-6.

¹⁷⁶ Watson R, et al. *Am Heart J Plus: Cardiol Res & Pract* 24, 2022; 1-6.

¹⁷⁷ Jain A, et al. *Heart Fail Rev.* 2016;21(5):611-9.

¹⁷⁸ Kazory A, et al. *Cardiorenal Med.* 2023;13:1-8.

¹⁷⁹ Costanzo MR, et al. *Val in Health.* 2018; 21(1): s167.

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AVOID-HF indicated distinct trends toward reduced time to heart failure events within 90 days, favoring the ultrafiltration group over diuretics. In addition, pre-specified secondary endpoints demonstrated significant reductions in heart failure rehospitalizations and days in the hospital and cardiovascular events at 30 days. No significant differences were observed in creatinine level between the groups during treatment and up to 90 days following treatment. In totality, AVOID-HF provided evidence that had AVOID-HF been followed to completion, it is our belief that the trial would likely have met its primary endpoint of improved outcome in acute decompensated heart failure patients.¹⁸⁰

One 2019 peer reviewed paper reported on a multicenter, retrospective case series of children who received kidney replacement therapy (KRT) with an ultrafiltration device.¹⁸¹ Patients were grouped according to weight and primary disease state (e.g. kidney, cardiac or other) and received one of three treatment modalities. The study found that of the 72 patients who weighed less than 10 kg, 43 or 60% survived to the end of therapy or transitioned to another modality of kidney support. 23 or 32% survived to hospital discharge. Among patients who weighed between 10-20 kg, 13 or 100% survived to the end of KRT treatment. Among patients who weighed more than 20 kg, 33 or 97% survived to KRT discontinuation and 23 or 68% survived to hospital discharge.¹⁸²

Product Development Activities

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

Corporate Development Activities

DaVita Supply and Collaboration Agreement

On June 19, 2023, we entered into a Supply and Collaboration Agreement (the “Supply Agreement”) with DaVita Inc., a Delaware corporation (“DaVita”), pursuant to which DaVita agreed to pilot the Aquadex ultrafiltration therapy system to treat adult patients with congestive heart failure and related conditions within select U.S. markets. The pilot program launched in June 2023 and extends through May 31, 2024 (the “Pilot”). Through the Pilot, ultrafiltration therapy using Aquadex will be offered at a combination of DaVita’s customer hospital and outpatient center locations, with both companies collaborating on the roll-out of the therapy, clinician training, and patient support. At the conclusion of the pilot, DaVita has the option, in its sole discretion, to extend the Supply Agreement with the Company for continued provision of both inpatient and outpatient ultrafiltration services for up to 10 years (“Ultrafiltration Services Approval”). DaVita reports that it has over 900 hospital partnerships, 2,500 clinics, over 6,500 employees and revenue of approximately \$11.6 billion for its 2022 fiscal year.

SeaStar License and Distribution Agreement

On December 27, 2022, we entered into an exclusive license and distribution agreement (the “Distribution Agreement”) with SeaStar Medical Holding Corporation (“SeaStar”), pursuant to which SeaStar appointed the Company as its exclusive distributor for the sale and distribution of SeaStar’s Selective Cytopheretic Device (“SCD-PED”) product throughout the United States following the receipt by SeaStar from the FDA of a written authorization to market such product for pediatric use pursuant to the Humanitarian Device Exemption (HDE) application submitted by SeaStar. The SCD-PED will provide a new therapy option for children weighing 10 kilograms or more who have acute kidney injury (AKI) and sepsis or a septic condition requiring continuous kidney replacement therapy (CKRT) in a hospital intensive care unit.

¹⁸⁰ Costanzo MR, et al. *Val in Health*. 2018; 21(1): s167.

¹⁸¹ Menon S, et al. *Clin J Am Soc Nephrol*. 2019 ;14(10):1432-1440.

¹⁸² Menon S, et al. *Clin J Am Soc Nephrol*. 2019 ;14(10):1432-1440.

Pursuant to the Distribution Agreement, SeaStar received an upfront payment, and is entitled to milestone payments upon achievement of certain milestones and royalties on gross sales of the SCD- PED product. The Distribution Agreement has an initial term commencing on December 27, 2022 and shall end on the three (3) year anniversary from the date that is the earlier of (a) ninety (90) days after SeaStar receives FDA authorization to market such SCD- PED product for pediatric use and (b) the first commercial sale of the SCD-PED product. The term of the Distribution Agreement may be automatically extended for additional terms of one (1) year and for a total of two (2) extensions. Each party has the right to terminate the Distribution Agreement for material breach if such breach is not cured within ninety (90) days after written notice. SeaStar has additional rights to terminate the Distribution Agreement in accordance with other terms set forth in the Distribution Agreement.

On October 31, 2023, we announced that SeaStar received an Approvable Letter from the FDA for its SCD-PED. The Approvable Letter indicated that SeaStar Medical's HDE application substantially meets the requirements for an Approval Order and outlined remaining administrative steps that must be finalized before the HDE can be active for commercialization. For the SCD-PED, these include revisions to product labeling and minor modifications to the post-approval study plan.

Our Strategy

Our vision is to transform the lives of patients suffering from fluid overload through science, collaboration and innovation. We provide healthcare professionals with a reliable, predictable, and easy-to-use mechanical pump and filtration system to remove excess fluid in fluid overloaded patients. We believe that our technology will provide a competitive advantage in the fluid management market by providing improved clinical benefits and reducing the cost of care relative to other treatment alternatives.

Our strategic focus is to demonstrate a strong business model by driving revenue growth. Growing revenue is the key metric employees, stockholders and potential investors will use to judge our performance. Our field-based employees include both sales representatives and clinical education specialists in 12 sales territories in the United States. We also have distribution agreements in several countries in Europe, South America, the Middle East, and Asia. We intend to focus on the acute needs of fluid overloaded patients in cardiac surgery and other areas of critical care, while continuing to support heart failure patients in the inpatient setting, and the outpatient setting. With our U.S. Food and Drug Administration ("FDA") 510(k) clearance for use in pediatric patients weighing 20kg or more, we have expanded our commercialization efforts to treatments for pediatric patients.

Critical Care: After we launched a marketing campaign focused on the benefits of the Aquadex System in treating patients suffering from fluid overload following cardiac surgery procedures, such as coronary artery bypass graft (CABG) surgery, valve repairs and replacements procedures, VAD implants and other cardiac surgical procedures. We then realigned our salesforce to further focus on the acute needs of fluid overloaded patients in the critical care setting. We believe that we will continue to grow revenue in this faster-growing segment of our business by leveraging the synergies between heart failure cardiologists and cardiovascular surgeons, traditional technology adoption rates of cardiac surgeons, and product purchase cycle of the cardiac surgical and other critical care centers at large hospitals.

Pediatrics: Ultrafiltration is used by physicians to treat fluid overload in various conditions in pediatric patients, including heart failure, cardiac surgery,¹⁸³ ECMO therapy,¹⁸⁴ solid organ transplantation,¹⁸⁵ and kidney replacement therapy for neonatal patients. In February 2020, the Company received 510(k) clearance for the Aquadex System to include pediatric patients who weigh 20kg or more. With this clearance, we expanded our commercialization efforts to include promotion to physicians and hospitals who treat this pediatric population, and we are investing in the development of new clinical evidence around use of ultrafiltration in pediatric patients, including the November 2020 launch of the ULTRA-Peds pediatrics registry, a multi-center, single-arm study. We are also investing in the development of a new dedicated pediatric device, to further address the needs of the pediatric population, and in clinical studies supporting the use of this device.

Heart Failure In-Patients: Heart failure patients suffering from fluid overload may be treated in an inpatient setting, such as a hospital, extended care facility or nursing home. Historically, our commercial efforts have been

¹⁸³ Elliott MJ. *Ann Thorac Surg.* 1993;56:1518-22. fluid overload

¹⁸⁴ Selewski DT, et al. *Crit Care Med.* 2012; 40(9): 2694-2699.

¹⁸⁵ Riley AA. *BMC Nephrology.* 2018; 19:268-80.

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primarily focused on use of the Aquadex System in the inpatient setting in large hospital accounts. We intend to continue to support our sales efforts on inpatient facilities, leveraging the clinical benefits and economic advantages of using the Aquadex System over diuretic therapy. We are investing in additional clinical evidence supporting the use of ultrafiltration in patients with decompensated heart failure including a multicenter, randomized controlled trial, the REVERSE-HF study, comparing ultrafiltration and IV diuretics.

Heart Failure Out-Patients: Further, we intend to expand the use of the Aquadex System with heart failure patients in the outpatient setting, such as an infusion clinic or hospital outpatient department (e.g., observation unit). On January 1, 2022, the American Medical Association (AMA) granted a new and dedicated Category III Current Procedural Terminology (CPT) code, 0692T, for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver ultrafiltration to adult and pediatric patients weighing more than 20kg. In addition, the new CPT code provides additional reimbursement for therapeutic ultrafiltration administered in the outpatient setting and will facilitate the migration of the therapy to this setting for a subset of the patient population due to hospital economic and patient quality of life benefits. Continued focus on driving positive coverage policies for various targeted payers will be an ongoing strategy for the Company.

Outside the United States, the Aquadex System is sold by independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. We currently have distribution relationships in Austria, Brazil, Colombia, Czech Republic, Germany, Greece, Hong Kong, India, Israel, Italy, Panama, Romania, Singapore, Slovak Republic, Spain, Switzerland, Thailand, United Arab Emirates and the United Kingdom. We intend to continue to establish distribution partners in additional countries outside of the United States. We received CE Mark Certification for our 24-Hour Blood Circuit Set in January 2022 to be used with the Aquadex SmartFlow® system. The CE marking allows us to market the 24-hour Blood Circuit in the European Union (EU) and all other countries that recognize this certification. This new circuit will help us expand access to ultrafiltration among patients who need no more than 24 hours of therapeutic ultrafiltration in the inpatient setting. Additionally, this circuit can provide a more economical solution for hospitals to treat patients in the outpatient/ambulatory setting, where therapy can be delivered for up to 8 hours. Such use in the outpatient setting provides us with the flexibility to better meet the clinical and healthcare economic needs of European markets, while at the same time improving lives by seeking to prevent hospitalizations.

Besides driving near-term revenue growth through sales of the Aquadex System, we intend to develop product enhancements to improve performance and customer satisfaction. We have projects designed to improve venous access for the Aquadex catheter and enhance the functionality of the hematocrit sensor that is part of the Aquadex console. As we expand our commercialization efforts in the pediatric market, we are developing a Continuous Renal Replacement Therapy (CRRT) console to address the unmet and specific needs of pediatric patients who do not have functioning kidneys and need kidney replacement therapy for survival. It is estimated that approximately 11,000 newborn babies require neonatal kidney replacement therapy each year in the United States.¹⁸⁶

Sales and Marketing

As of December 31, 2023, we had 24 full-time employees in sales and marketing. We have 12 sales territories in the United States. Our U.S. field salesforce includes sales managers, account managers and clinical education specialists who provide training, technical and other support services to our customers. Following the acquisition of the business associated with the Aquadex System (the “Aquadex Business”) from Baxter International, Inc. (“Baxter”) in August 2016, our direct salesforce was focused initially on re-engaging hospital accounts that had ordered Aquadex blood sets in prior years, re-educating customers on the therapy, and assessing each hospital’s use of the Aquadex System to gain additional opportunity for increased utilization, primarily in heart failure. In 2018, we expanded our commercialization efforts to include post-cardiac surgery. In September 2019, we realigned our salesforce to further focus on the acute needs of fluid overloaded patients in the critical care setting, while still supporting heart failure. We expanded our commercialization efforts to include pediatrics, following receipt of 510(k) clearance of the Aquadex system to include pediatric patients who weigh 20kg or more in February 2020.

¹⁸⁶ <https://www.ncbi.nlm.nih.gov/pubmed/23833312>

In the United States, our target customers for the Aquadex System include healthcare systems and academic hospitals specializing in advanced treatment of chronic heart failure and/or critical care patients. With the 510(k) clearance of the Aquadex SmartFlow® system for patients weighing over 20kg, we are also targeting pediatric hospitals. Our largest customer represented 12.5% of our 2022 annual revenue. The loss of this customer would have a material adverse effect on our revenue

Clinical Experience

Several large-scale, multi-center, randomized, controlled trials have evaluated the use of ultrafiltration using the Aquadex System on patients with acute decompensated heart failure compared to standard-of-care treatment with intravenous diuretics. These trials followed early-stage studies which primarily focused on safety of ultrafiltration treatment with the Aquadex System.

The UNLOAD trial enrolled 200 patients and showed that average weight and fluid loss were greater in the ultrafiltration group 48 hours following randomization. No differences were noted in symptoms of dyspnea between the groups. In addition, through 90 days of follow-up, the ultrafiltration group experienced fewer re-hospitalizations and unscheduled medical visits for heart failure, while renal function assessed by serum creatinine level was not significantly different between the groups.

The CARRESS trial studied 188 randomized acute decompensated heart failure patients over the course of 96 hours and found no difference in weight loss and an increase in creatinine level relative to the control group treated with intravenous diuretics. The creatinine increase was interpreted as a sign of potential worsening renal function in the ultrafiltration group. Results of CARRESS have been criticized on several limitations including the methodology and protocol, particularly that trial results were impacted by centers unfamiliar with the use of ultrafiltration therapy, that more than one third of the ultrafiltration group received diuretics instead of ultrafiltration, ultrafiltration rates were fixed rather than utilizing adjusted ultrafiltration rates according to patient characteristics whereas diuretic doses were titrated based on urine output, and that the diuretic regimen employed was not representative of standard-of-care.¹⁸⁷ In addition, subsequent analyses of the CARRESS study cohort have been published since the original study results. One protocol analysis showed that ultrafiltration had higher net fluid loss and weight reduction compared to intravenous diuretics, and there were no significant differences in long-term outcomes.¹⁸⁸ An additional sub-study analysis on urinary biomarkers showed that although further worsening creatinine levels were reported, decongestion and renal function recovery at 60 days were superior in patients with increased tubular injury markers.¹⁸⁹ The data suggests that the benefits of decongestion may outweigh modest or transient increases in serum creatinine during ultrafiltration. Thus, a change in creatinine should not dissuade the use of ultrafiltration.

Disparate results between UNLOAD and CARRESS led to initiation of the AVOID-HF trial by Baxter. AVOID-HF was designed to prospectively address the question of patient outcomes when treated with ultrafiltration versus intravenous diuretics for acute decompensated heart failure. Trial design assumptions indicated that 810 patients would need to be randomized to achieve adequate statistical power. However, the study was terminated by Baxter at 224 patients, apparently for business reasons unrelated to patient outcomes or device safety. Despite being underpowered, the results of AVOID-HF indicated distinct trends toward reduced time to heart failure events within 90 days, favoring the ultrafiltration group over diuretics. In addition, pre-specified secondary endpoints demonstrated significant reductions in heart failure rehospitalizations and days in the hospital and cardiovascular events at 30 days. No significant differences were observed in creatinine level between the groups during treatment and up to 90 days following treatment. In totality, AVOID-HF recapitulated the results of both UNLOAD and CARRESS while providing evidence that had AVOID-HF been followed to completion, it is our belief that the trial would likely have met its primary endpoint of improved outcome in acute decompensated heart failure patients.

In November 2020, we launched the ULTRA-PEDs pediatrics registry, a multi-center, single-arm study currently being conducted at seven clinical sites. The study is currently enrolling with 88 patients enrolled to date.

¹⁸⁷ Urban S, et al. *Adv Clin Exp Med*. 2021;30(7):737-746.

¹⁸⁸ Grodin JL, et al. *Eur J of Heart Fail*. 2018;20(7):1148-1156.

¹⁸⁹ Rao VS, et al. *Circ Heart Fail*. 2019;12 (6):e005552.

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In May 2021, a third-party systemic evaluation of eight randomized controlled trials, “*Ultrafiltration is better than diuretic therapy for volume-overloaded acute heart failure patients: a meta-analysis*,”¹⁹⁰ studied the effectiveness of ultrafiltration therapy compared to diuretics in 801 patients hospitalized with acute decompensated heart failure. The meta-analysis demonstrated ultrafiltration increases fluid removal and weight loss and reduces rehospitalization and the risk of worsening heart failure in congestive patients, suggesting ultrafiltration is a safe and effective treatment option for volume-overloaded heart failure patients.

In December 2021, we launched the REVERSE-HF prospective, multicenter, randomized controlled trial (RCT) to evaluate ultrafiltration compared to IV diuretics in patients with heart failure. This RCT is currently being conducted at nine clinical sites nationwide, and patient enrollment began in June 2022.

In February 2022, a third party retrospectively reviewed and concluded, “*The Use of Ultrafiltration as a fluid management strategy for High-Risk Coronary Artery Bypass Grafting*,”¹⁹¹ that ultrafiltration is a safe and effective modality to manage fluid balance in a patient population with relatively high Society of Thoracic Surgery (STS) scores, but a prospective multicenter study would be warranted in this patient cohort.

A reanalysis of the AVOID-HF data was presented at the Annual Scientific Session of the Heart Failure Society of America in September 2022, “*Revisiting The Aquapheresis Versus Intravenous Diuretics And Hospitalizations For Heart Failure (AVOID-HF) Trial: Further Evidence Supporting Aquapheresis To Reduce Heart Failure Events*,”¹⁹² using the novel Finkelstein-Schoenfeld method of hierarchical win ratio (WR) to explore cardiovascular (CV) mortality and heart failure (HF) events. adjustable ultrafiltration (AUF) was compared to adjustable loop diuretics (ALD) with respect to a primary composite endpoint of CV mortality within 90 days, HF event within 30 days, and time to first heart failure event within 90 days, with HF event defined as HF rehospitalization, unscheduled outpatient or emergency department treatment with IV loop diuretics or vasoactive drugs, or unscheduled outpatient ultrafiltration. The WR analysis yielded results favoring ultrafiltration, demonstrating that AUF is safe and more effective than ALD in reducing CV mortality and subsequent HF events for hospitalized heart failure patients. Secondary analysis of HF events and rehospitalizations within 30 and 90 days, without mortality, statistically favored ultrafiltration.

In December 2022, a third-party, single center, real-world retrospective study of 335 patients treated with the Aquadex FlexFlow® System, “*Ten Year Real World Experience with Ultrafiltration for the Management of Acute Decompensated Heart Failure*,”¹⁹³ compared previous randomized controlled clinical trials with ultrafiltration and demonstrated that ultrafiltration compares favorably in reducing heart failure rehospitalizations (2.14 hospitalizations per year before Aquadex versus 0.4 hospitalizations per year one year after Aquadex), renal function response, and weight/volume loss. The study found ultrafiltration to be safe with regard to renal function (unchanged) despite the cohort in this study being sicker than those studied in other clinical trials, and that UF can be a safe and effective strategy for decongestion in clinical practice wherein the benefits outweigh the potential risks of kidney dysfunction requiring hemodialysis and major bleeding events.

In January 2023, we began designing an Investigational Device Exemption (IDE) clinical study for the Company’s dedicated pediatric device currently under development. The study is anticipated to begin enrollment in early 2024.

Research and Development

Research and Development costs include activities related to development, design, and testing improvements to the Aquadex System and potential related products. The Aquadex system software may require periodic modifications for feature additions and performance improvements. We will make such design changes as needed based on proactive and reactive mechanisms. Research and development costs also include expenses related to our clinical research.

In 2020, we initiated a product development project designed to improve peripheral venous access for the Aquadex FlexFlow® catheter and minimize filter clotting during the use of the Aquadex System and in 2021 initiated a product development project designed to enhance the functionality of the hematocrit sensor that is part of the Aquadex console. In 2021, we also initiated a product development project to develop a pediatric

¹⁹⁰ Urban S, et al. *Adv Clin Exp Med*. 2021;30(7):737-746.

¹⁹¹ Beckles D, et al. *J of Card Surg. Fail*. 2022; 37(10): 2951-2957.

¹⁹² Pinney S, et al. Poster from Heart Failure Society of America Meeting; October 2022; Washington, DC.

¹⁹³ Hass DC, et al. *Amer Heart J Plus.; Cardio Res & Pract* 2022; 24:1-6 (100230)

continuous renal replacement therapy device. We successfully completed functional system prototypes in 2022 and initiated qualification activities in 2023. We are also evaluating diagnostic tools for physicians to use during an Aquadex therapy to more precisely determine the amount of excess fluid to be removed, the rate of ultrafiltration, and when to stop therapy as dry weight is approached.

Manufacturers and Suppliers

We manufacture the Aquadex System at our 23,000 square foot facility in Eden Prairie, Minnesota. We have manufactured the Aquadex SmartFlow® console and blood circuits since its development in 2019. We purchase parts and components for the Aquadex System from third-party manufacturers and suppliers. We believe that our current manufacturing facility is suitable and adequate to meet anticipated manufacturing demands, and that, if necessary, suitable additional or substitute space will be available to accommodate expansion of our operations.

Intellectual Property

We have submitted patent applications to establish an intellectual property portfolio through which we seek to protect our system and technology. In connection with our acquisition of the Aquadex Business, we entered into a patent license agreement with Baxter pursuant to which we obtained, for no additional consideration, a worldwide license to 49 exclusively licensed and 9 non-exclusively licensed patents used in connection with the Aquadex System to make, have made, use, sell, offer for sale and import the Aquadex System in the “field of use.” Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven “required maintenance patents,” and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. We estimate that the patents licensed from Baxter will expire by mid-2026.

We have twenty pending patent applications. The first application includes multiple features and capabilities to assist patient fluid balance and to enhance usability for healthcare providers. The second application involves a vacuum pump-controlled wearable appliance to increase vein diameter and venous flow for peripheral ultrafiltration. The third application involves plasma and blood volume measurement to guide ultrafiltration therapy. The fourth application involves features and functions for ultrafiltration for pediatric patients. The fifth application involves a dual-lumen ultrafiltration catheter for enhanced peripheral access. The sixth application involves guidance of ultrafiltration therapy based on one or more diagnostic parameters. The seventh application involves a system for ensuring maintenance of peripheral venous flow during ultrafiltration and other CKRT modalities. The eighth application enhances patient fluid balance through control of an ultrafiltration system.

In addition, as of January 30, 2024, 16 issued patents are assigned to Nuwellis in the United States and in foreign jurisdictions related to our technology, the C-Pulse® Heart Assist System (the “C-Pulse System”) for treatment of Class III and ambulatory Class IV heart failure. We estimate that most of our currently issued U.S. patents will expire by 2026. Given the strategic refocus away from the C-Pulse System and toward the Aquadex System, we have chosen to limit the maintenance of issued C-Pulse System related patents to those innovations that are of high value. Further, we have elected to emphasize important jurisdictions rather than maintain protection in multiple countries. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any financial return. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to obtain commercial benefits from them.

We have developed technical knowledge that, although non-patentable, we consider to be significant in enabling us to compete. It is our policy to enter into confidentiality agreements with each of our employees and consultants prohibiting the disclosure of any confidential information or trade secrets. In addition, these agreements provide that any inventions or discoveries by employees and consultants relating to our business will be assigned to us and become our sole property.

Despite our patent rights and policies regarding confidential information, trade secrets and inventions, we may be subject to challenges to the validity of our patents, claims that our system infringes the patent rights of others, and the disclosure of our confidential information or trade secrets. These and other risks are described more fully under the heading “Risk Factors” in this prospectus.

At this time, we are not a party to any legal proceedings that relate to patents or intellectual property rights or any other subject matter.

Competition

Competition from medical device companies and medical device divisions of healthcare companies, pharmaceutical companies and gene- and cell-based therapies is intense and expected to increase. The vast majority of patients with fluid overload receive pharmacological treatment (diuretics) as the standard of care. There are no direct competitors for the Aquadex System in heart failure or critical care in the United States, other than diuretics. Other systems, such as Baxter's Prismaflex, a filter-based device that is approved for continuous renal replacement therapy for patients weighing 20kg or more with acute renal failure and/or fluid overload, represent indirect competitors, as they can only be used to conduct ultrafiltration with significant limitations. In pediatrics, the Carpediem system distributed by Medtronic is indicated for use in acute kidney injury or fluid overloaded patients requiring hemodialysis or hemofiltration therapy, and Baxter's HF20 Set is authorized under an Emergency Use Authorization to deliver CRRT to treat patients of low weight (8-20kg) in an acute care environment during the COVID-19 pandemic. Additionally, Medtronic and DaVita have recently formed a joint venture, called Mozarc Medical, to pursue a variety of kidney applications across each of our customer categories.

Our ability to compete effectively depends upon our ability to demonstrate the advantages of ultrafiltration as compared to diuretics, a pharmacological treatment that is currently the standard of care. In addition, we need to distinguish the Aquadex System from the indirect competition of other devices that can also be used to conduct ultrafiltration.

Third-Party Reimbursement

In the United States, our products are purchased primarily by customers such as hospitals or other healthcare providers. Customers bill various third-party payers for covered services provided to patients. These payers, which include federal healthcare programs (e.g., Medicare and Medicaid), state healthcare programs, private health insurance companies, and managed care organizations, then reimburse our customers based on established payment formulas that consider part or all of the costs associated with these devices and the related procedures performed.

While the agency responsible for administering the Medicare program, the Centers for Medicare and Medicaid Services, has not issued a favorable national coverage determination under its Investigational Device Exemption Studies Program for ultrafiltration using the Aquadex System, a number of private insurers have approved reimbursement for use of the products included in the Aquadex System for specific indications and points of service. In addition, patients and providers may seek insurance coverage on a case-by-case basis. On January 1, 2022, a new and dedicated Category III Current Procedural Terminology (CPT) code, 0692T, became effective for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver ultrafiltration to adult and pediatric patients weighing more than 20kg. The new CPT code provides additional reimbursement for therapeutic ultrafiltration administered in the outpatient setting.

Legislative proposals can substantially change the way healthcare is financed by both governmental and private insurers and may negatively impact payment rates for our system. Also, from time to time, there are numerous legislative, regulatory and other proposals both at the federal and state levels that may impact payment rates for our system. It remains uncertain whether there will be any future changes that will be proposed or finalized and what effect, if any, such legislation or regulations would have on our business. However, in the United States and international markets, we expect that both government and third-party payers will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged, or deny coverage, for healthcare products and services.

Government Regulations

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the manufacture and marketing of our current system and any future products and in our ongoing research and development activities. In particular, medical devices are subject to rigorous preclinical testing as a condition of 510(k) clearance by the FDA and by similar authorities in foreign countries. Any proposed products will require regulatory clearance/approval prior to commercialization.

United States

The Federal Food, Drug, and Cosmetic Act (“FDC Act”) and the FDA’s implementing regulations govern medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDC Act, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market medical devices that are regulated by the FDA, comparable state agencies and regulatory bodies in other countries.

Unless an exemption applies, each medical device we intend to commercially distribute in the U.S. will require 510(k) clearance.

510(k) Clearance. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is “substantially equivalent” to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. The 510(k) clearance process cannot exceed 90 days from the date the FDA accepts the 510(k) submission. After a device has received 510(k) clearance for a specific indication for use, any modification to that device that could “significantly affect its safety or effectiveness,” such as a significant change in the design, materials, method of manufacture or which results in “major change” to the product performance, may require a new 510(k) clearance. The determination as to whether new 510(k) is needed is initially left to the manufacturer; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing the modified device until 510(k) clearance is received.

The Aquadex FlexFlow system was granted FDA 510(k) clearance for commercial use on June 3, 2002. On February 4, 2020, we received 510(k) clearance of the Aquadex SmartFlow® system for use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management. The Aquadex SmartFlow incorporates diagnostic tools for physicians to use during an Aquadex therapy to more precisely determine the amount of excess fluid to be removed, the rate of ultrafiltration, and when to stop therapy as dry weight is approached.

Clinical Trials. To obtain FDA clearance to market certain devices, clinical trials may be required to support a 510(k) application. Clinical trials generally require submission of an application for an Investigational Device Exemption (IDE) to the FDA prior to commencing the trial. FDA approval of an IDE allows clinical testing to go forward but does not bind the FDA to accept the results of the trial as sufficient to prove the product’s safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with regulations and requirements collectively known as “Good Clinical Practices”. Good Clinical Practices include the FDA’s IDE regulations, which describe the conduct of clinical trials with medical devices. They also prohibit promotion, test marketing or commercialization of an investigational device and any representation that such a device is safe or effective for the purposes being investigated. Good Clinical Practices also include the FDA’s regulations for institutional review board approval and for protection of human subjects (such as informed consent), as well as disclosure of financial interests by clinical investigators. Required records and reports are subject to inspection by the FDA.

The results of clinical trials may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant clearance of a product. The commencement or completion of any clinical trial may be delayed or halted or be inadequate to support clearance of a 510(k) application for numerous reasons.

Continuing Regulation. After a device is cleared for use and placed in commercial distribution, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing upon the commencement of manufacturing;
- the Quality System Regulation (QSR), which requires manufacturers, including third-party manufacturers, to follow the FDA design control regulations;

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- labeling regulations, which prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections; and
- product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDC Act caused by the device that may present a risk to health.

In addition, the FDA may require a company to conduct post-market surveillance studies or order it to establish and maintain a system for tracking its products through the chain of distribution to the patient level.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters or untitled letters;
- fines, injunctions and civil penalties;
- product recall or seizure;
- unanticipated expenditures;
- delays in clearing or refusal to clear products;
- withdrawal or suspension of FDA clearance;
- orders for physician notification or device repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials; or
- criminal prosecution.

We and our contract manufacturers are also required to manufacture our products in compliance with Current Good Manufacturing Practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

European Union

In order to import and sell our products in member countries of the European Union, or EU, medical devices currently must comply with the essential requirements of the European Union Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the Conformité Européenne, or CE, Mark (“CE Mark”) to our products, without which they cannot be sold or marketed in the EU. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the European Union Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body, an organization accredited by a member state of the EU to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of

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our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

The EU Medical Device Regulation 2017/745 (MDR) was adopted in April 2017. The MDR replaces the existing Medical Device Directives (MDD [93/42/EEC](#) and AIMDD [90/385/EEC](#)). The new MDR went into effect on May 26, 2021, and the new CE Mark product must comply with new MDR or AIMDD 90/385/EEC after this date. As of May 26, 2021, companies that have devices on the market with CE Mark under MDD 93/42/EEC or AIMDD 90/385/EEC must meet the transitional provisions of the new MDR. Devices lawfully placed on the market under MDD 93/42/EEC or AIMDD 90/385/EEC before May 26, 2021, may continue to be made available on the market until May 27, 2024, provided the CE Mark was issued prior to this date, the manufacturer continues to comply with either one of the directives, and that no significant changes are made in the design and intended purpose of the applicable medical device. Recently EU parliament issued an amendment and approved the new timeline for EU MDR compliance. The new timeline is now December 31, 2028. All medical devices entering the EU after December 31st, 2028, will need to have a new CE Mark under the MDR, even if they have been on the market previously under the MDD/AIMDD. The amendment also removes the date after which devices can no longer be made available (“sell-off” deadline). Legacy devices can therefore continue to be made available on the market and put into service after 26/05/2025. This removal applies unconditionally: devices that will not be brought into compliance with the MDD regulation are also beneficiaries. Manufacturers are required to update their technical documentation and processes to meet the new MDR regulations. Nuwellis received the CE Mark for Aquadex SmartFlow® on January 13, 2020. Nuwellis received the renewal certificate to include the 24-Hour blood circuit on September 3, 2021. Our CE certificate for Aquadex SmartFlow® System is under MDD/93/42 EEC and is valid through May 26, 2024, which allows us to sell the Aquadex SmartFlow® System into the EU and satisfy future distribution demand. We plan before May 26, 2024, file a formal application and sign a contract with our Notified Body GMED for Aquadex SmartFlow certification to new MDR and extend our EC certificate beyond May 26, 2024.

Any one or more of these factors associated with international operations could increase our costs, reduce our revenues, or disrupt our operations, which could have a material adverse effect on our business, financial condition, and results of operations.

Market Information

Commencing February 16, 2012, our shares of common stock began trading on Nasdaq, where it now trades under the symbol “NUWE.”

Stockholders of Record. As of December 31, 2023, we had 5,682,461 shares of common stock issued and outstanding, and there were 3 holders of record of our common stock. A substantially greater number of stockholders may be “street name” or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividends. We have not historically paid cash dividends on our capital stock. We intend to retain our future earnings, if any, to finance the expansion and growth of our business, and we do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of future cash dividends, if any, will be at the sole discretion of our board of directors after considering various factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with any debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay any dividends in the future, there can be no assurance that we will continue to pay such dividends.

Employees

As of December 31, 2023, we had 59 full-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Properties

We lease a 23,000 square foot facility located in Eden Prairie, Minnesota for office and manufacturing space under a non-cancelable operating lease that expires in March 2027. In November 2021, the Company entered into a fourth amendment to the lease, extending the term of the lease from March 31, 2022 to March 31, 2027.

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This facility serves as our corporate headquarters and houses substantially all our functional areas. Monthly rent and common area maintenance charges, including an estimate for property taxes for our headquarters, total approximately \$34,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease.

We believe that our current facilities are suitable and adequate to meet our current needs, and that suitable additional or substitute space will be available as needed to accommodate expansion of our operations.

Legal Proceedings

We are not currently subject to any legal proceedings.

Company History

Prior to July 2016, we were focused on developing the C-Pulse System for treatment of Class III and ambulatory Class IV heart failure. In August 2016, we acquired the Aquadex Business from a subsidiary of Baxter. In September 2016, we announced a strategic refocus of our strategy that included halting all clinical evaluations of the C-Pulse System related technology to fully focus our resources on our recently acquired Aquadex Business. On April 27, 2021, we announced that we were changing our name from CHF Solutions, Inc. to Nuwellis, Inc. to reflect the expansion of our customer base from treating fluid imbalance resulting from congestive heart failure to also include critical care and pediatrics applications.

Corporate Information

Nuwellis, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Limited, which dissolved as a wholly owned Australian subsidiary of Nuwellis, Inc. in 2020. Our common stock began trading on the Nasdaq Capital Market on February 16, 2012.

Our principal executive offices are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is (952) 345-4200. Our website address is www.nuwellis.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These reports are also available on the SEC's website, www.sec.gov. The information on, or that may be accessed through, any websites noted herein is not incorporated by reference into and should not be considered a part of this prospectus.

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 may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. As long as we remain a smaller reporting company and 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 the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

We give careful attention to related person transactions because they may present the potential for conflicts of interest. Under SEC rules, a related person transaction is any transaction or series of transactions in which: the Company or a subsidiary is a participant; the amount involved exceeds the lesser of \$120,000 or 1% of the average of the Company's total assets at year-end for the last two completed fiscal years; and a related person has a direct or indirect material interest. A "related person" is a director, executive officer, nominee for director or a more than 5% stockholder, and any immediate family member of the foregoing.

To identify related person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. We maintain a written policy for the review, approval or ratification of related person transactions, and our Audit Committee reviews all related person transactions identified by the Company. The Committee approves or ratifies only those related person transactions that are determined by it to be, under all of the circumstances, in the best interests of the Company and its stockholders.

The Company engaged in no related party transactions required to be reported under Item 404 of Regulation S-K for the fiscal years ended December 31, 2023, 2022 and 2021.

MANAGEMENT

Directors and Executive Officers

The following table sets forth certain information regarding our directors and executive officers as of December 31, 2023:

Name	Age	Position(s)	Director Class – Term Ending
Nestor Jaramillo, Jr.	66	President & Chief Executive Officer; Director	Class I – 2026
Robert B. Scott	44	Chief Financial Officer	N/A
Neil P. Ayotte	60	Senior Vice President, General Counsel and Chief Compliance Officer	N/A
John L. Erb	74	Chairman of the Board; Director	Class III – 2025
Maria Rosa Costanzo	69	Director	Class II – 2024
Archelle Georgiou, M.D.	61	Director	Class II – 2024
Michael McCormick	62	Director	Class I – 2026
David McDonald	63	Director	Class I – 2026
Gregory D. Waller	74	Director	Class III – 2025

Our board of directors is currently composed of seven members. Our directors are elected for three-year staggered terms. The two Class II directors will hold office until the 2024 annual meeting of stockholders. The two Class III directors will hold office until the 2025 annual meeting of stockholders. The three Class I directors will hold office until the 2026 annual meeting of stockholders.

Our executive officers are elected by our board of directors and hold office until removed by the board of directors, and until their successors have been duly elected and qualified or until their earlier resignation, retirement, removal, or death.

Specific Qualifications, Attributes, Skills and Experience to be Represented on the Board

The Nominating and Corporate Governance Committee of the Board is responsible for reviewing and assessing with the Board the appropriate skills, experience and background sought of Board members in the context of our business and the then-current membership on the Board. The Nominating and Corporate Governance Committee and the Board review and assess the continued relevance of and emphasis on these factors as part of the Board’s annual self-assessment process and in connection with candidate searches to determine if they are effective in helping to satisfy the Board’s goal of creating and sustaining a Board that can appropriately support and oversee the Company’s activities.

We believe our directors have an appropriate balance of knowledge, experience, attributes, skills and expertise as a group to ensure that the Board appropriately fulfills its oversight responsibilities and acts in the best interests of our stockholders. Although specific qualifications for Board membership may vary from time to time, desired qualities include (i) the highest ethical character, integrity and shared values with the Company, (ii) relevant expertise upon which to be able to offer advice and guidance to management, (iii) sound business judgment, and (iv) sufficient commitment and availability to effectively carry out a director’s duties. Listed below are additional key skills and experience that we consider important for our directors to have in light of our current business and structure. Thereafter, the biographies of the directors and nominees set forth their business experience during at least the past five years, as well as the specific experience, qualifications, attributes and skills that led to the Nominating and Corporate Governance Committee’s conclusion that each director and nominee should continue to serve on the Board.

- **Industry Experience.** We are an early-stage medical device company focused on commercializing our Aquadex SmartFlow® system. Experience in the medical device industry is useful in understanding our business strategy, the regulatory environment we face within the United States and abroad and our primary competitors.
- **Senior Leadership Experience.** Directors who have served in senior leadership positions can provide experience and perspective in analyzing, shaping, and overseeing the execution of important operational, organizational and policy issues at a senior level.

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- Financial and Accounting Expertise. Knowledge of the financial markets, corporate finance, accounting regulations, and accounting and financial reporting processes can assist our directors in understanding, advising, and overseeing our capital structure, financing activities, financial reporting, and internal control of such activities. The Company also strives to have at least one director who qualifies as a financial expert under SEC rules.
- Public Company Board Experience. Directors who have served on other public company boards can offer advice and insights with regard to the dynamics and operation of a board of directors, the relations of a board to the chief executive officer and other management personnel, the importance of particular agenda and oversight matters, and oversight of a changing mix of strategic, operational, governance and compliance-related matters.
- Business Development and Mergers and Acquisitions Experience. Directors who have background in business development and in mergers and acquisitions transactions can provide insight into developing and implementing strategies for growing our business, which may include mergers and acquisitions. Useful experience in mergers and acquisitions includes an understanding of the importance of “fit” with the Company’s culture and strategy, the valuation of transactions, and management’s plans for integration with existing operations.

Background and Qualifications

Nestor Jaramillo, Jr. has served as our president and chief executive officer and as a member of our Board since January 2021. Previously, he served as our president and chief operating officer from July 2020 to January 2021 and our chief commercial officer from May 2019 to July 2020. From October 2017 to May 2019, Mr. Jaramillo served as president and chief executive officer of Innerspace Neuro Solutions, Inc., a commercial-stage medical technology company that developed, manufactured and distributed an intracranial pressure monitoring system. Mr. Jaramillo also served on the board of directors of two private companies: NPI Medical, Inc, from May 2014 to September 2017 and Accu-Mold Corp. from January 2012 to May 2017. From May 2014 to September 2017, Mr. Jaramillo was managing director of healthcare investment banking at Craig-Hallum Capital, based in Minneapolis, Minnesota, and from March 2010 to April 2014, he was managing director of healthcare investment banking at Cherry Tree & Associates, based in Minneapolis, Minnesota. Mr. Jaramillo has also served in a variety of roles at Transoma Medical from 2007 to 2010, St. Jude Medical from 2006 to 2007, and at Medtronic plc from 1982 to 2006. In these roles, his responsibilities included leading sales and marketing teams both in the United States and internationally, where he spent five years in Europe. Mr. Jaramillo received an M.B.A. from the University of St. Thomas and a B.S. in Electrical Engineering from the University of North Dakota.

Mr. Jaramillo’s qualifications to serve on our Board include his multiple years in leadership positions in the medical device industry, including his role as chief executive officer of Innerspace Neuro Solutions, Inc., and his multiple years in investment banking.

Robert B. Scott has served as Chief Financial Officer of the Company since September 2023. Immediately prior to his appointment as Chief Financial Officer of the Company, Mr. Scott served as the Company’s Senior Finance Director from June 2022 to September 2023. Mr. Scott has held various positions of increasing responsibility with the Company in finance, strategic planning and financial reporting. Mr. Scott joined the Company in 2013. Prior to joining the Company, Mr. Scott served as the Finance Director from 2011 to 2013 at Entrepreneurial Advantage, a digital marketing start-up company, and from 2006 to 2011, Mr. Scott served in various finance roles at UnitedHealth Group (NYSE:UNH). He is a graduate of the University of Minnesota, Carlson School of Management, where he earned a Bachelor of Science in Finance and Entrepreneurial Studies.

Neil Ayotte has served as Senior Vice President, General Counsel, Secretary and Chief Compliance Officer since June 2021. He was formerly Executive Vice President, General Counsel and Secretary for Bluestem Group, Inc. a \$1.8 billion, private equity sponsored, e-commerce and mail order retailer from February 2017 to August 2020. From January 2015 to January 2017, Mr. Ayotte was Chief Legal Counsel for Medtronic’s Americas Region, the largest of Medtronic’s four super regions. During his 16-year tenure at Medtronic, Mr. Ayotte was the Chief Legal Counsel to the Integration Management Office, dedicated exclusively to leading Medtronic’s integration of its \$49 billion acquisition of Covidien plc, and he also served as Medtronic’s Interim General Counsel in 2013. Mr. Ayotte holds a J.D. from the University of Minnesota Law School, an M.A. from the University of Wisconsin and a B.A. from St. Mary’s University of Minnesota.

As described above, Mr. Ayotte served as an executive officer of Bluestem Group, Inc. and its various subsidiaries, including Bluestem Brands, Inc. which filed for bankruptcy protection in Delaware in March 2020. Bluestem Brands, Inc. emerged from bankruptcy in late August 2020.

Except as described in the preceding sentence, no other event has occurred during the past 10 years related to Mr. Ayotte or any other executive officer requiring disclosure pursuant to Item 401(f) of Regulation S-K.

John L. Erb has served as a director of the Company since September 2012 and as chairman of our Board since October 2012. Previously, Mr. Erb served as president and chief executive officer from November 2015 to January 2021. He was executive chairman of the board (during 2007) and chief executive officer (from 2001 to 2006) of the previous owner of the Aquadex™ system, which was also known as CHF Solutions, Inc., a medical device company involved in the development, manufacturing and distribution of devices to treat congestive heart failure. Mr. Erb previously served as chief executive officer (from 2007 to 2020) of NuAx, Inc. (formerly Cardia Access, Inc.), a medical device company involved in developing new devices for the treatment of heart disease; president and chief executive officer of IntraTherapeutics, Inc., a medical device company involved in the development, manufacturing and distribution of peripheral vascular stents, from 1997 to 2001; and in various positions, including as vice president of worldwide operations at Schneider, a division of Pfizer, Inc., from 1991 to 1997. Mr. Erb's prior board experience includes service as a director of SenoRx, Inc., (a Nasdaq listed company), from December 2001 to July 2010; service as a director of CryoCath Technologies Inc., (a publicly traded Canadian company), from October 2000 to December 2008; and service as director of Vascular Solutions, Inc., (a Nasdaq listed company) from 2002 to 2019, where he also served as chairman of the Board (from 2011 to 2017) and chairman of the compensation and nominating and corporate governance committees. Mr. Erb served as a director and chief executive officer of NeuroMedic, Inc., a private company, from 2010 to 2020, when NeuroMedic was acquired by ReCor Medical, Inc. Mr. Erb currently serves as president and chief executive officer of CRS Teknologies, Inc., a private company whose primary business is the development of diagnostic and therapeutic products to treat cardiorenal syndrome; serves as chairman of the board of Osprey Medical, Inc., a private company dedicated to improving heart imaging procedures, where he also serves as a member of the compensation and audit committees; serves as chairman of the board for IR Medtek, a private company developing oncology products; and as a director of Miromatrix (Nasdaq: MIRO). Mr. Erb received a B.A. in business administration, with a concentration in finance, from California State University, Fullerton.

With over 40 years of experience in the medical device industry, including 20 years of experience serving as chief executive officer of medical device companies, Mr. Erb brings to our Board valuable business, management and leadership experience, as well as a deep understanding of the challenges presented in growing a medical device company. In addition, his role on the boards of Osprey Medical, Vascular Solutions, SenoRx and CryoCath Technologies has provided him with other public company board experience. Having managed significant operations of a multi-national medical device company, Mr. Erb also contributes valuable private company operational experience.

Maria Rosa Costanzo, M.D. has served as a director of the Company since September 2019. Dr. Costanzo has served as the medical director, Heart Failure Research, at Advocate Heart Institute, and the medical director for Advanced Heart Failure at Edward Hospital Center in Illinois since 2002. From 1994 until 2001, Dr. Costanzo served as the medical director of the Heart Failure/Cardiac Transplant Program at Rush University Medical Center and was the John H. and Margaret V. Krehbiel Professor of Cardiology at the Rush Medical College. From 1988 to 1994, she served as medical director of the Loyola University Chicago Heart Failure and Cardiac Transplant Program. From 1995 until 2000, Dr. Costanzo was also the editor in chief of the Journal of Heart and Lung Transplantation. In 2002, she was appointed by the Secretary of Health and Human Services to a four-year term on the National Heart, Lung and Blood Institute Advisory Council. Since 2012, Dr. Costanzo has been a member of the American Board of Internal Medicine exam writing committee for the specialty of Advanced Heart Failure and Transplant Cardiology. Dr. Costanzo currently serves on the board of directors for the Heart Failure Society of America. In addition, she is a member of several medical societies and a fellow with the American College of Cardiology, American College of Physicians, American Heart Association, and the European Society of Cardiology, and a Gold Member of the Heart Failure Association of the European Society of Cardiology. She is also a member of the Ordine Dei Medici (The Italian National Medical Professional Association). Dr. Costanzo received her medical degree with honors from Facolta' Di Medicina e Chirurgia dell' Universita' di Bologna in Bologna, Italy.

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Dr. Costanzo's qualifications to serve on our Board include her years of clinical medical experience in cardiac care, in particular heart failure, including her experiences leading multi-center clinical trials and serving as a board member and fellow on international medical societies.

Archelle Georgiou, M.D. has served as a director of the Company since November 2023. Dr. Georgiou is the President of Georgiou Consulting, LLC. Since January 2008, Georgiou Consulting, LLC has offered strategic advisory services to companies committed to consumer-centered healthcare. Dr. Georgiou has held executive leadership positions in managed care, investment banking, and medical device companies. She has served as Chief Medical Officer and senior executive at UnitedHealth Group from March 1995 to December 2007. She's served as Chief Medical Officer and Chief Health Officer at Starkey Hearing Technologies from January 2020 to December 2022, Chairman of the Board of Directors at Children's Hospital and Clinics of Minnesota since February 2022 and Executive in Residence at the University of Minnesota's Carlson School of Management since July 2014. From May 2016 through May 2019, she was a Director for Tivity Health, Inc. and served on the governance and compensation committees. She has additional previous experience serving on public as well as non-profit boards. Dr. Georgiou is a published author and has over 16 years of experience as an on-air TV medical correspondent where she simplifies complex healthcare information for viewers. Dr. Georgiou received her M.D. degree from the Johns Hopkins School of Medicine and was board-certified in Internal Medicine.

Dr. Georgiou's qualifications to serve on our Board include her years of clinical medical experience in internal medicine and her understanding of complex medical information.

Michael McCormick has served as a director of the Company since May 2023. Mr. McCormick is a seasoned executive with over 25 years of experience in leading medical device companies and serving as a board member for several private and publicly-traded life science companies. From 2010 to 2023, Mr. McCormick served as CEO of Osprey Medical (ASX: OSP), an interventional cardiology commercial stage medical device company focused on technologies to reduce Contrast Induced Acute Kidney Injury. From 2003 to 2008, Mr. McCormick was CEO of Anulex Technologies Inc., a private company focused on developing proprietary technologies to support the healing of spinal soft tissues that was successfully sold to Boston Scientific. Prior to this, Mr. McCormick was President of Centerpulse Spine-Tech, a publicly traded full line supplier of innovative spinal technologies. Mr. McCormick was involved in the successful sale of Centerpulse Spine-Tech to Zimmer in the fall of 2003. Early in his career, Mr. McCormick worked at Boston Scientific Scimed and Baxter Health Care where he served in a variety of sales and sales management roles. Mr. McCormick is a member of the Board of Directors of Osprey Medical, Inc., and Formae, Inc. and previously the Chairman of OrthoCor Medical, which was sold in 2019, and a director of Cardio Renal Society of America and of Anulex Technologies, Inc. Mr. McCormick received his Bachelor of Business Administration, Business Management from The University of Texas at Austin.

Mr. McCormick's qualifications to serve on our Board include his 25-plus years of experience in leading medical device companies and experience with publicly held companies.

David McDonald has served as a director of the Company since November 2023. Mr. McDonald is the head of Life Science Investment Banking at Lake Street Capital Markets. Immediately prior to joining Lake Street, Mr. McDonald worked in the oncology industry serving as a Senior Financial and Business Development Executive for SillaJen Biotherapeutics from June 2013 to December 2015, Delcath Systems from September 2009 to May 2013 and AngioDynamics from July 2008 to September 2009. In addition, Mr. McDonald has over 35 years of capital markets experience, serving the needs of emerging growth companies as a healthcare investment banker, equity research analyst, and investor with RBC Capital Markets from May 2000 to June 2005, Investment Advisors, Inc. from September 1994 to February 2000, Wessels, Arnold & Henderson (since acquired by RBC) from January 1989 to September 1994, American Express from June 1986 to December 1989 and Adams, Harkness & Hill (since acquired by Canaccord Genuity) from September 1982 to May 1986. Mr. McDonald received his BA in Economics from St. Olaf College.

Mr. McDonald's qualifications to serve on our Board include his experience in healthcare investment banking, advising clients on hundreds of merger and acquisition and financing transactions.

Gregory D. Waller has served as a director of the Company since August 2011. Mr. Waller also serves on the board of directors of Arcadia Bioscience, Inc., a publicly traded company (and as chairman of the audit committee and a member of the compensation committee). Until April 2015, Mr. Waller was chief financial officer of Ulthera Corporation, a privately held company that sells an ultrasound device used for non-invasive

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brow lifts, which was sold to Merz North America in July 2014. From March 2006 to April 2011, Mr. Waller was chief financial officer of Universal Building Products, Inc., a manufacturer of concrete construction accessories. Mr. Waller served as vice president of finance, chief financial officer, and treasurer of Sybron Dental Specialties, Inc., a manufacturer and marketer of consumable dental products, from August 1993 until his retirement in May 2005, and was formerly vice president and treasurer of Kerr, Ormco Corporation, and Metrex. Mr. Waller joined Ormco in December 1980 as vice president and controller and served as vice president of Kerr European Operations from July 1989 to August 1993. Mr. Waller received an M.B.A. with a concentration in accounting from California State University, Fullerton. His prior board service includes service as a director for the following companies: Alsius Corporation, a publicly traded company (chairman of the audit committee and a member of the compensation committee), from June 2007 until its acquisition by Zoll Medical Corporation in September 2009; Biolase Technology, Inc., a publicly traded company (chairman of the audit committee), from October 2009 to August 2010; Cardiogenesis Corporation, a publicly traded company (chairman of the audit committee), from April 2007 until its acquisition by Cryolife in May 2011; Clariant, Inc., a publicly traded company that was acquired by General Electric Company in December 2010 (chairman of the audit committee and a member of the compensation and corporate governance committees), from December 2006 to December 2010; Endologix Corporation, a publicly traded company (chairman of the audit committee and member of the nominating and governance committee), from November 2003 until its reorganization in October 2020 and SenoRx, a publicly traded company that was acquired by C.R. Bard, Inc. in July 2010 (chairman of the audit committee), from May 2006 to July 2010.

Mr. Waller's qualifications to serve on our Board include his 48 years of financial and management experience, including his experiences as chief financial officer of Universal Building Products, Sybron Dental Specialties, and Ulthera Inc., as well as his familiarity with public company board functions from his service on the boards of other public companies.

As described above, Mr. Waller served as a director of Endologix Corporation from 2003 to 2020. Endologix Corporation filed a voluntary petition for bankruptcy on July 5, 2020. Except as described in the preceding sentence, no other event has occurred during the past 10 years regarding any other director requiring disclosure pursuant to Item 401(f) of Regulation S-K.

BOARD MATTERS

The Board of Directors

General

Our Board has general oversight responsibility for our affairs and, in exercising its fiduciary duties, represents and acts on behalf of our stockholders. Although our Board does not have responsibility for our day-to-day management, it stays regularly informed about our business and provides oversight and guidance to our management through periodic meetings and other communications. Our Board provides critical oversight in our strategic planning process, as well as other functions carried out through our Board's committees as described below.

Director Independence

Our Board believes that there should be at least a majority of independent directors on our Board. Our Board undertakes a review of director independence in accordance with Nasdaq listing rules at least once annually. The independence rules include a series of objective tests, including that the director is not employed by us and has not engaged in various types of business dealings with us. In addition, our Board is required to make a subjective determination as to each independent director that no relationships exist which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our Board reviewed and discussed information provided by the directors to us with regard to each director's business and personal activities as they may relate to us and our management.

Our Board has affirmatively determined, after considering all of the relevant facts and circumstances, that Mr. Brandt, who retired from the Board in January 2023, Mr. Salveson, who resigned from the Board in October 2023, and Mr. Watson, who resigned from the Board in June 2023, were independent directors while serving as a member of the Board, and Dr. Costanzo, Dr. Georgiou, Mr. McCormick, Mr. McDonald, and Mr. Waller, are independent directors under the applicable rules of Nasdaq, which consists of all of our directors

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except for Mr. Erb, former chief executive officer and president and current Chairman of the Board, and Mr. Jaramillo, our President and Chief Executive Officer. Mr. McCormick serves as our lead independent director. Each member of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee is independent under Nasdaq rules. In addition, our Board has affirmatively determined that the members of the Audit Committee and Compensation Committee qualify as independent in accordance with the additional independence rules established by the SEC and Nasdaq.

Director Compensation

Our non-employee directors receive a mix of cash and share-based compensation. The compensation mix is intended to encourage non-employee directors to continue Board service, further align the interests of the Board and stockholders and attract new non-employee directors with outstanding qualifications. Directors who are our employees or officers do not receive any additional compensation for service on the Board.

2023 Director Compensation Table

The table below sets forth the compensation of each non-employee director from January 1, 2023 through December 31, 2023.

As a named executive officer of the Company, compensation paid to Mr. Jaramillo for the 2022 and 2023 fiscal years is fully reflected under “Named Executive Officer Compensation Tables—Summary Compensation Table for 2023 and 2022.”

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) ⁽¹⁾⁽³⁾	Total (\$)
Steve Brandt ⁽⁴⁾	15,167	0	15,167
Maria Rosa Costanzo, M.D.	53,792	0 ⁽²⁾	53,792
John Erb	60,000	5,859	65,859
Archelle Georgiou, M.D. ⁽⁵⁾	0	0	0
Michael McCormick ⁽⁶⁾	25,664	0	25,664
David McDonald ⁽⁷⁾	0	0	0
Jon W. Salveson ⁽⁸⁾	53,750	5,859	59,609
Gregory D. Waller	63,000	5,859	68,859
Warren S. Watson ⁽⁹⁾	49,326	5,859	55,185
Total	<u>320,699</u>	<u>23,436</u>	<u>344,135</u>

- (1) This amount reflects stock options granted under the 2013 Directors’ Plan on May 19, 2023. The amounts reported represent the grant date fair value of the stock options. Valuation assumptions used in determining the grant date fair value are included in Note 4 to the condensed consolidated financial statements for the quarter ended September 30, 2023, which are included in this prospectus. The grant date fair value per share of the stock options granted on May 19, 2023 to all directors was approximately \$2.73 per share.
- (2) Dr. Costanzo elected not to receive any equity compensation for her role as a director.
- (3) As of December 31, 2023, each non-employee director had the following number of shares underlying outstanding options (both vested and unvested): Dr. Costanzo 0; Mr. Erb 2,391, Dr. Georgiou 0; Mr. McCormick 0, Mr. McDonald 0, and Mr. Waller 2,408.
- (4) Mr. Brandt resigned from the Board effective January 16, 2023.
- (5) Dr. Georgiou was appointed to the Board effective November 1, 2023.
- (6) Mr. McCormick was appointed to the Board effective June 1, 2023.
- (7) Mr. McDonald was appointed to the Board effective November 1, 2023.
- (8) Mr. Salveson resigned from the Board effective October 31, 2023.
- (9) Mr. Watson resigned from the Board effective June 2, 2023.

Our Non-Employee Director Compensation Policy, which was adopted in May 2019, (and amended in August 2021 upon the retirement of Mr. Erb, and further amended and restated in January of 2023 following FW Cook’s market assessment of non-employee director compensations across our peer group) provides for annual cash and equity compensation. Each non-employee director receives annual cash compensation of \$45,000, the lead independent director receives an additional \$10,000 per year and the Chair of the Board receives an additional \$15,000 per year. Directors also receive annual cash compensation for service on committees. For the Audit Committee, the chair now receives \$15,000 per year and each other member receives

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\$7,500 per year. For the Compensation and the Nominating and Corporate Governance Committees, the chair receives \$10,000 per year and each other member receives \$5,000 per year. Cash compensation is paid in four quarterly installments following completion of the applicable quarter.

Under the Amended and Restated Non-Employee Director Compensation Policy, in addition to cash compensation outlined above, each director received an annual stock option award of the number of shares equal to 0.40% of the total common shares outstanding of the Company on December 31, 2023, granted on the date of the annual meeting of stockholders with 1/12th of the shares underlying the awards vesting monthly so that all of the underlying shares are vested on the one-year anniversary of the grant date. We do not provide any perquisites to directors.

Stockholder Communication with the Board

Any stockholder wishing to communicate with a particular director, with all or certain of the non-employee or independent directors, or with the entire Board should direct the communication to Secretary, Nuwellis, Inc., 12988 Valley View Road, Eden Prairie, Minnesota 55344. In general, any communication delivered to the Company for forwarding to the Board or specified Board member or members will be forwarded in accordance with the instructions. However, the Company reserves the right not to forward to Board members any abusive, threatening or otherwise inappropriate materials.

EXECUTIVE COMPENSATION

Summary Compensation Table for 2023 and 2022

The following table sets forth certain information for the years ended December 31, 2023 and 2022 regarding compensation of our named executive officers.

Name and Principal Position	Year	Salary (\$)	Option Awards (\$) ⁽¹⁾⁽²⁾	Non-equity Incentive Plan Compensation (\$)	All Other Compensation (\$) ⁽³⁾	Total (\$)
Nestor Jaramillo, Jr. President & Chief Executive Officer	2023	420,582	168,891	109,351	17,130	715,953
	2022	412,337	86,238	199,117	17,022	714,714
Robert B. Scott Chief Financial Officer ⁽⁴⁾	2023	243,157	38,811	46,745	9,442	338,154
	2022	—	—	—	—	—
Lynn L. Blake Former Chief Financial Officer ⁽⁵⁾	2023	248,681	99,982	—	11,040	359,702
	2022	65,417	—	26,744	642	92,803
Neil P. Ayotte SVP, General Counsel & Chief Compliance Officer	2023	326,457	63,945	80,798	16,083	487,283
	2022	289,848	22,434	92,165	9,104	413,551

- (1) Reflects a stock option granted under the Company’s New Hire Equity Incentive Plan or 2021 Inducement Plan, as applicable.
- (2) The fair value of each stock option is estimated at the grant date using the Black-Scholes option pricing model. The fair value of stock options under the Black-Scholes option pricing model requires management to make assumptions regarding projected employee stock option exercise behaviors, risk-free interest rates, volatility of the Company’s stock price and expected dividends, if any.
- (3) For each named executive officer, amounts include employer matching contributions made on the officer’s behalf to the Company’s 401(k) Plan, contributions to the officer’s health savings account and Company payments for life insurance premiums.
- (4) Mr. Scott was promoted to Chief Financial Officer of the Company effective September 2, 2023.
- (5) Ms. Blake resigned as Chief Financial Officer effective September 1, 2023.

Narrative Discussion of Summary Compensation Table for 2023

Employment Agreements and Other Arrangements. Mr. Jaramillo has a written employment agreement. We signed offer letters with Mr. Scott, Ms. Blake and Mr. Ayotte upon their respective commencement of employment with us. All of the named executive officers have change in control agreements, which entitle them to payments from the Company upon the happening of specified termination events. See “— Potential Payments Upon Termination or Change in Control” for descriptions of these agreements.

Base Salaries. The initial annual base salaries of our executive officers are negotiated in connection with their hiring. The Compensation Committee reviews the base salaries of the executive officers on an annual basis and generally grants salary increases following such reviews.

As discussed above under “Board Matters—Board Committees—Compensation Committee” and “—Role of Compensation Consultant,” the Compensation Committee engaged FW Cook in 2020 to conduct a review of our executive compensation program. Based on the advice and information from FW Cook and taking into account information from publicly available industry surveys, the Compensation Committee approved base salary increases in 2023 ranging from 3% to 7% for our officers and, specifically, a 3% merit increase and a 4.1% special adjustment for Mr. Jaramillo, to bring his base salary to 90% of a median benchmark salary and a 1.7.% increase for Mr. Ayotte.

Equity Compensation. In 2022, Mr. Jaramillo received an option to purchase 1,011 shares of common stock at an exercise price of \$94 per share effective March 3, 2022, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. Mr. Ayotte received an option to purchase 263 shares of common stock at an exercise price of \$94 per share effective March 3, 2022, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant

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date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. In 2023, pursuant to a first amendment to the Blake Offer Letter, Ms. Blake received an option to purchase 12,417 shares of common stock at an exercise price of \$8.36 per share effective January 6, 2023, with vesting as follows: 25% of the options will vest on October 19, 2023 with the remaining shares vesting in 36 equal consecutive monthly increments thereafter, so that all shares will be vested on October 19, 2026, all of which were forfeited upon Ms. Blake's resignation on September 1, 2023. Mr. Ayotte received an option to purchase 8,640 shares of common stock at an exercise price of \$7.72 per share effective March 3, 2023, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. Mr. Jaramillo received options to purchase 8,954 and 13,866 shares of common stock, respectively, each at an exercise price of \$7.72 per share effective March 3, 2023, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. Mr. Scott received options to purchase 18,643 shares of common stock, at an exercise price of \$1.79 per share effective September 2, 2023, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date.

Non-equity Incentive Plan Compensation. In 2023, the target bonus as a percentage of annual base salary for Mr. Jaramillo was 65%, for Ms. Blake the target bonus was 45%, for Mr. Scott the target bonus was 40%, and for Mr. Ayotte it was 45%.

The earned bonus was based on the achievement of corporate performance objectives established and weighted by the Compensation Committee, in consultation with our chief executive officer, and primarily related to our annual revenue, the number of clinical sites active under the REVERSE-HF clinical trial and selected product development milestones related to the Company's dedicated pediatric dialysis device, which is under development. The Compensation Committee assessed our achievement of the corporate objectives at 2022 year-end and calculated a total weighted average performance to corporate objectives of 87.8%. While Mr. Jaramillo's bonus was based solely on the achievement of corporate objectives, Mr. Scott, Ms. Blake and Mr. Ayotte were also compensated based on the achievement of individual personal objectives, which accounted for 25% of their overall bonus. Because her employment with the Company commenced in October 2022, Ms. Blake's bonus was pro-rated for her time with the Company in 2022. Similarly, Mr. Scott's bonus was also prorated to reflect his promotion with the Company in September 2023.

The following table sets forth target and earned non-equity incentive plan compensation for 2022 and 2023.

Name	2022			2023		
	Target	Earned		Target	Earned	
	% of Base Salary	\$	\$	% of Base Salary	\$	\$
Nestor Jaramillo, Jr.	55	226,785	199,117	65	273,378	109,351
Lynn Blake	45	29,438	26,744	45	0	0
Robert B. Scott	25	60,789	44,828	40	74,743	46,745
Neil Ayotte	35	101,447	92,165	45	146,906	80,798

Offer Letter – Ms. Blake

On September 30, 2022, we entered into an offer letter with Ms. Blake (the "Blake Offer Letter"), which was subsequently amended on December 6, 2022, regarding her employment as our Chief Financial Officer effective October 19, 2022. Ms. Blake was offered an annualized salary of \$325,000, paid in monthly installments in accordance with the Company's payroll procedures. Ms. Blake was also made eligible for a bonus of up to 45% of her base salary. Ms. Blake received an option to purchase 12,417 shares of our common stock at an exercise price of \$8.36 per share effective January 6, 2023. Ms. Blake was also made eligible to participate in the employee stock option program and benefit programs generally made available to employees. Ms. Blake resigned from her position with the Company effective September 1, 2023.

Offer Letter – Mr. Scott

On August 17, 2023, we entered into an offer letter with Mr. Scott (the “Scott Offer Letter”) regarding his employment as our Chief Financial Officer effective September 2, 2023. Mr. Scott was offered an annualized salary of \$280,000, paid in monthly installments in accordance with the Company’s payroll procedures. Mr. Scott was also made eligible for a bonus of up to 40% of his base salary. Mr. Scott received an option to purchase 18,643 shares of our common stock at an exercise price of \$1.79 per share effective September 2, 2023. Mr. Scott was also made eligible to participate in the employee stock option program and benefit programs generally made available to employees.

Offer Letter – Mr. Ayotte

On May 21, 2021, we entered into an offer letter with Mr. Ayotte regarding his employment as our SVP, General Counsel and Chief Compliance Officer, effective as of June 7, 2021. Mr. Ayotte was offered an annualized salary of \$300,000, paid in monthly installments in accordance with the Company’s payroll procedures. Mr. Ayotte was also made eligible for a bonus of up to 45% of his base salary and was made eligible to participate in the employee stock option program and benefit programs generally made available to employees. Mr. Ayotte received an option to purchase 263 shares of our common stock at an exercise price of \$94 per share effective March 3, 2022 and an option to purchase 8,640 shares of common stock at an exercise price of \$7.72 per share effective March 3, 2023.

Outstanding Equity Awards at Fiscal Year-End 2023

The following table sets forth certain information concerning equity awards held by our named executive officers that were outstanding as of December 31, 2023.

Name	Option Awards ⁽¹⁾			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Nestor Jaramillo, Jr.	28	—	10,260.00	5/22/2029
	92	35	930.00	1/22/2031
	1,019	560	363.00	5/19/2031
	442	569	94.00	3/3/2032
	—	22,820	7.72	3/3/2033
Lynn Blake	—	—	—	—
Robert B. Scott	9	3	930.00	1/22/2031
	38	21	359.00	5/18/2031
	22	30	94.00	3/3/2032
	—	1,133	7.72	3/3/2033
	—	18,643	1.79	9/2/2033
Neil P. Ayotte	260	156	398.00	6/22/2031
	115	148	94.00	3/3/2032
	—	8,640	7.72	3/3/2033

(1) The underlying shares vest as follows: 25% of the shares vest on the one-year anniversary of the grant date; the remaining shares vest in 36 equal consecutive monthly installments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date.

Potential Payments Upon Termination or Change in Control

Equity Compensation Plans

Equity awards have been issued to the named executive officers under the 2017 Plan, 2011 Plan, the New Hire Plan, and the Nuwellis, Inc. 2021 Inducement Plan (the “2021 Inducement Plan”). A termination or change in control may affect the vesting and/or exercisability of awards issued under the equity compensation plans, as further discussed below.

- Stock Options. Generally, if a participant’s continuous service terminates:
 - other than for cause or upon the participant’s death or disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date three months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.
 - upon the participant’s disability, the participant may exercise his or her option (to the extent the option was vested as of the date of termination) within such period of time ending on the earlier of (i) the date 12 months following the termination or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate as a result of the participant’s death, or if the participant dies within the period during which the option may be exercised after the termination of the participant’s continuous service for a reason other than death, the option may be exercised (to the extent the option was vested as of the date of death) by the participant’s estate within the period ending on the earlier of (i) the date 18 months following the date of death or (ii) the expiration of the term of the option. If the option is not exercised within such period, it will terminate.
 - for cause, the option will terminate upon the date of termination, and the participant will be prohibited from exercising his or her option from and after such time.

Acceleration of Vesting. Under the 2017 Plan, the New Hire Plan and the 2021 Inducement Plan, the Board or the Compensation Committee may accelerate the exercisability or vesting of an award at any time, including immediately prior to a participant’s termination or change of control.

Change in Control Agreements

We have entered into change in control agreements with the named executive officers that require us to provide compensation to the officer in the event of a change in control. Each agreement has a term that runs from its effective date through the later of: (i) the five-year anniversary of the effective date, subject to automatic extension for successive two-year periods until notice of non-renewal is given by either party at least 60 days prior to the end of the then-effective term; or (ii) if a change in control occurs on or prior to the end of the then-effective term, then the one-year anniversary of the effective date of such change in control.

The change in control agreements provide that, if: (x) a change in control occurs during the term of the officer’s agreement; and (y) the officer’s employment terminates anytime during the one-year period after the effective date of the change in control; and (z) such termination is involuntary at the Company’s initiative without cause or is due to the officer’s voluntary resignation for good reason, then the Company will: (i) pay in a lump sum the officer’s salary for 12 months and any other earned but unpaid compensation; (ii) pay in a lump sum an amount equal to the incentive bonus payment received by the officer for the fiscal year immediately preceding the fiscal year in which the termination occurs; and (iii) provide healthcare benefits to the officer and the officer’s family until the earlier of (A) the date 12 months after the officer’s termination and (B) the date the officer is, and/or the officer’s covered dependents are, eligible to receive group medical and/or dental insurance coverage by a subsequent employer.

We are also obligated to make the foregoing payments and to provide the foregoing healthcare benefits in the event (i) the officer’s employment terminates (A) due to a voluntary resignation for good reason or (B) due to an involuntary termination by the Company without cause, and (ii) a change in control occurs within 90 days after the termination date and during the term of the agreement.

In addition to the payments described above, each change in control agreement provides that if a change in control occurs while the officer is actively employed by the Company and during the term of the agreement,

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such change in control will cause the immediate acceleration of the vesting of 100% of any unvested portion of any stock option awards held by the officer on the effective date of such change in control.

We are not obligated to make the payments described above unless: (i) the officer signs a full release of any and all claims in favor of the Company; (ii) all applicable consideration periods and rescission periods have expired; and (iii) as of the dates we provide any payments to the named executive officer, the officer is in strict compliance with the terms of the applicable change in control agreement and any proprietary information agreement the officer has entered into with the Company.

Employment Agreement – Mr. Jaramillo

On January 16, 2021, we entered into an executive employment agreement with Mr. Jaramillo regarding his employment as our Chief Executive Officer and President. The employment agreement replaced the offer letter with Mr. Jaramillo dated April 12, 2019.

The employment agreement had an initial term (the “Initial Term”) of 12 months beginning on January 16, 2021 and automatically renews for an additional 12-month period at the end of the Initial Term and each anniversary thereafter, provided that at least 90 days prior to the expiration of the Initial Term or any renewal term the Board does not notify Mr. Jaramillo of its intention not to renew the employment period.

The agreement entitles Mr. Jaramillo to, among other benefits, the following compensation:

- An annual base salary initially set at \$385,000, to be reviewed at least annually (currently \$420,582 for 2023);
- An opportunity for Mr. Jaramillo to receive an annual performance bonus in an amount of up to fifty-five percent (55%) (currently sixty-five percent (65%) as of 2023) of Mr. Jaramillo’s annual base salary for such fiscal year based upon achievement of certain performance goals to be established by the Board;
- An opportunity to receive equity awards as determined by the Compensation Committee of the Board based on Mr. Jaramillo’s performance;
- Prior to January 31, 2023, an opportunity to receive a stock option to purchase a number of shares of the Company’s common stock equal to 2.4% of the outstanding shares of common stock and preferred stock calculated on an as-converted basis to shares of the Company’s common stock basis, following approval of the Board. In connection therewith, in May 2021, Mr. Jaramillo was awarded a stock option to acquire 1,579 shares of the Company’s common stock at an exercise price of \$363 per share;
- Participation in welfare benefit plans, practices, policies and programs provided by the Company and its affiliated companies (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) to the extent available generally or to other senior executive officers of the Company;
- Prompt reimbursement for all reasonable expenses incurred by Mr. Jaramillo in accordance with the plans, practices, policies and programs of the Company; and
- Twenty-two (22) days paid time off (PTO), to accrue and to be used in accordance with the Company’s policies and practices in effect from time to time, as well as all recognized Company holidays.

In connection with the equity grant contemplated by the agreement, Mr. Jaramillo received an option to purchase 127 shares of our common stock at an exercise price of \$930 per share effective January 22, 2021.

The agreement also includes a “claw-back” provision providing for the recoupment of unearned incentive compensation if the Board, or an appropriate committee thereof, determines that Mr. Jaramillo engaged in any fraud, negligence, or intentional misconduct that caused or significantly contributed to the Company having to restate all or a portion of its financial statements, or if we are required to seek reimbursement by applicable laws or regulations, the Board or committee may require reimbursement of any bonus or incentive compensation paid to Mr. Jaramillo.

Upon termination of Mr. Jaramillo’s employment, Mr. Jaramillo may be entitled to certain payments and benefits, depending on the reason for his termination. In the event Mr. Jaramillo resigns his employment without good reason, the Company terminates Mr. Jaramillo’s employment for cause, or Mr. Jaramillo’s employment

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terminates as a result of his death or disability, Mr. Jaramillo is entitled to receive the Unconditional Entitlements, but not the Conditional Benefits (each as defined below). In the event Mr. Jaramillo resigns with good reason or the Company terminates Mr. Jaramillo's employment for a reason other than cause, Mr. Jaramillo is entitled to receive the Unconditional Entitlements, as well as the Conditional Benefits, provided that Mr. Jaramillo signs and delivers to the Company, and does not revoke, a general release of claims in favor of the Company and certain related parties.

The "**Unconditional Entitlements**" include the following: (i) any annual base salary earned, but unpaid, for services rendered to the Company on or prior to the date on which the employment period ends; (ii) in the event Mr. Jaramillo's employment terminates after the end of a fiscal year but before payment of the annual bonus payable for his services rendered in that fiscal year, the annual bonus that would have been payable to Mr. Jaramillo for such completed fiscal year, provided that such termination is not due to the Company's termination of Mr. Jaramillo for cause or Mr. Jaramillo's resignation without good reason; and (iii) certain other benefits contemplated by the agreement.

The "**Conditional Benefits**" include the following: (i) a lump sum amount equal to Mr. Jaramillo's annual base salary as of the termination date; (ii) continued medical coverage for 12 months following the termination date; (iii) continued vesting of equity awards for 12 months following the termination date; and (iv) a pro-rata annual bonus for the year in which the termination date occurs, determined on the basis of an assumed full-year target bonus and the number of days in the applicable fiscal year occurring on or before the termination date.

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 December 31, 2023 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 December 31, 2023, there were 5,682,461 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	4	5,861 ⁽³⁾	5,865	*
Michael McCormick	—	—	—	*
Maria Rosa Costanzo, M.D.	—	—	—	—
Archelle Georgiou, M.D.	—	—	—	*
Gregory D. Waller	—	1,872	1,872	*
David McDonald	—	—	—	
Robert B. Scott	—	74	74	*
Nestor Jaramillo, Jr.	4,098	1,694	5,792	*
Neil P. Ayotte	—	403	403	*
Lynn Blake	100	—	100	*
All current directors and executive officers as a group (9 persons)	4,202	9,904	14,106	*%

* 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 December 31, 2023.
- (2) Based on 5,682,461 shares outstanding as of December 31, 2023.
- (3) Consists of (i) 1,855 shares issuable upon the exercise of outstanding stock options, (ii) 6 shares issuable upon the exercise of outstanding warrants to purchase common stock, and (iii) 4,000 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 CAPITAL STOCK

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

The shares of common stock, pre-funded warrants, and common warrants that we are offering are immediately separable and will be issued separately.

Common Stock

Our authorized capital stock consists of 100,000,000 shares of common stock, par value \$0.0001 per share, and 40,000,000 shares of preferred stock, par value \$0.0001 per share, 30,000 of which are designated as Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F Convertible Preferred Stock (the “Series F Preferred Stock”), and 600,000 of which are designated Series J Convertible Preferred Stock (the “Series J Convertible Preferred Stock”) as of December 31, 2023. 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 December 31, 2023, we had (i) 5,682,461 outstanding shares of common stock, (ii) 127 outstanding shares of Series F Preferred Stock, which, at the currently applicable conversion price, would convert into 125,857 shares of common stock, subject to future adjustment, (iii) 11,950 outstanding shares of Series J Convertible Preferred Stock, which, at the currently applicable conversion price, would convert into 295,792 shares of common stock, subject to future adjustment, (iv) outstanding options to acquire 110,916 shares of our common stock, (v) outstanding warrants to purchase 2,963,192 shares of our common stock, (vi) 66,917 Series J Convertible Preferred Stock underlying the warrants issued in the October 2023 Offering, and (vii) 295,792 shares of common stock underlying the outstanding Series J Convertible Preferred Stock.

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

Dividends

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

Voting

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

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

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

Conversion, Redemption and Preemptive Rights

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

Liquidation, Dissolution and Winding-up

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

Listing

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

Preferred Stock

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

Prior to issuance of shares of any series of preferred stock, our board of directors is required by Delaware law to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware.

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The certificate of designation fixes for each class or series the terms, preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends or other distributions, qualifications and terms or conditions of redemption for each class or series. Any shares of preferred stock will, when issued, be fully paid and non-assessable.

Outstanding Series F Convertible Preferred Stock.

The following describes the material terms of the Series F Convertible Preferred Stock. This is not a complete description and is subject to, and entirely qualified by reference to applicable provisions of our Certificate of Incorporation, Bylaws and the Certificate of Designations establishing the Series F Convertible Preferred Stock, which are filed with the SEC as exhibits to the registration statement of which this prospectus is a part, as well as the relevant portions of Delaware law. Capitalized terms used but not defined in this subsection shall have the meanings ascribed to them in the Certificate of Designations establishing the 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 December 31, 2023, there were 127 shares of Series F Preferred Stock outstanding with a conversion price of \$1.01.

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.

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 \$1.01 (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 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.

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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 Equiniti Trust Company, LLC, formerly American Stock Transfer & Trust LLC 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.

Outstanding Series J Convertible Preferred Stock

The following describes the material terms of the Series J Convertible Preferred Stock. This is not a complete description and is subject to, and entirely qualified by reference to applicable provisions of our Certificate of Incorporation, Bylaws and the Certificate of Designations establishing the Series J Convertible Preferred Stock, which are filed with the SEC as exhibits to the registration statement of which this prospectus is a part, as well as the relevant portions of Delaware law. Capitalized terms used but not defined in this subsection shall have the meanings ascribed to them in the Certificate of Designations establishing the Series J Convertible Preferred Stock.

Our board of directors designated 600,000 shares of preferred stock as Series J convertible preferred stock, \$0.0001 par value. As of December 31, 2023, there were 11,950 shares of Series J Convertible Preferred Stock outstanding with a stated value of \$25.00.

In addition, subject to the limitations described herein, we may issue additional preferred stock from time to time in one or more series, each with such designation, powers, preferences and relative, participating, optional or other special rights, and the qualifications, limitations or restrictions applicable to any of those rights, including dividend rights, voting rights, conversion or exchange rights, terms of redemption and liquidation preferences, as the Board (or a duly authorized committee of the Board) may determine prior to the time of such issuance.

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

Transfer Agent and Registrar. The transfer agent and registrar for the Series J Convertible Preferred Stock will be Equiniti Trust Company, LLC (the “Transfer Agent”). The Transfer Agent’s address is 6201 15th Avenue, Brooklyn, NY, 11219. The Series J Convertible Preferred Stock will be issued and maintained in book-entry form registered in the name of the nominee, The Depository Trust Company. See “– Book-Entry Procedures” below.

Maturity. The Series J Convertible Preferred Stock matures three (3) years from the closing date of the offering.

Ranking and Liquidation Preference. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, prior and in preference to the common stock, holders of the Series J Convertible Preferred Stock shall be entitled to receive out of the assets available for distribution to stockholders an amount equal in cash to 100% of the aggregate Stated Value of \$25.00 per share (the “Stated Value”) of all shares of Series J Convertible Preferred Stock held by such holder, and any other fees then due and owing thereon under the Certificate of Designations, and no more, and if the assets of the Company shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the holders shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Dividends. The Certificate of Designations shall provide that dividends on the Series J Convertible Preferred Stock shall be paid in-kind in additional shares of Series J Convertible Preferred Stock based on the stated value of \$25.00 per share at the annual dividend rate of 20% and a quarterly dividend rate of 5% (the “Quarterly Dividend Rate”). The PIK dividends will be paid on a quarterly basis for three (3) years following the Closing Date to holders of the Series J Convertible Preferred of record at the close of business at the end of October 31,

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January 31, April 30, and July 31 of each year (each a “Dividend Record Date”) at the Quarterly Dividend Rate. PIK dividends on each share of Series J Convertible Preferred Stock shall be paid three business days after each Dividend Record Date in additional fully paid and nonassessable, registered shares of Series J Convertible Preferred Stock in a number equal to the quotient obtained by dividing (A) the product obtained by multiplying (i) the Quarterly Dividend Rate and (ii) the stated value of \$25.00 per share, by (B) \$15.00.

Conversion. The Series J Convertible Preferred Stock is convertible at any time at the option of the holder. Except as provided below, the Series J Convertible Preferred Stock is not convertible into or exchangeable for any other securities or property.

Conversion at Option of Holder. Each share of Series J Convertible Preferred Stock is convertible at the option of the holder at any time into shares of our common stock at the Conversion Price of \$1.01, which was the closing price of our common stock on the Nasdaq Capital Market on October 12, 2023, which Conversion Price is subject to adjustment. The Conversion Price is subject to adjustment for: (i) the payment of stock dividends or other distributions payable in common stock on the outstanding shares of our common stock, excluding the shares of common stock issuable upon the conversion of the Series J Convertible Preferred Stock; and (ii) subdivisions and combinations (including by way of a reverse stock split).

Holders shall effect conversions of the Series J Convertible Preferred Stock by providing us a conversion notice (a “Notice of Conversion”), duly completed and executed. The Notice of Conversion must specify the number of shares of Series J Convertible Preferred Stock then held by the holder and the number of such shares which the holder is converting. To effect conversions of shares of Series J Convertible Preferred Stock, a holder shall not be required to surrender the certificate(s), if any, representing the shares of Series J Convertible Preferred Stock to us unless all of the shares of Series J Convertible Preferred Stock represented thereby are so converted, in which case such holder shall deliver the certificate representing such shares of Series J Convertible Preferred Stock promptly following the conversion date at issue. Shares of Series J Convertible Preferred Stock converted into our shares of common stock shall be canceled and shall not be reissued.

If, at any time while the Series J Convertible Preferred Stock is outstanding: we (A) pay a stock dividend or otherwise make a distribution or distributions payable in shares of our common stock or any other Common Stock Equivalents (which, for avoidance of doubt, shall not include any shares of common stock issued by us upon conversion of the Series J Convertible Preferred Stock, or payment of a dividend on the Series J Convertible Preferred Stock) with respect to the then outstanding shares of common stock; (B) subdivide outstanding shares of common stock into a larger number of shares; (C) combine (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares or (D) issue, in the event of a reclassification of shares of the common stock, any shares of our capital stock, which we refer to collectively as the “Anti-Dilution Provisions”, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of common stock (excluding any treasury shares) outstanding immediately before such event and of which the denominator shall be the number of shares of common stock outstanding immediately after such event (excluding any treasury shares). Any adjustment made as a result of the Anti-Dilution Provisions shall become effective immediately after the record date for the determination of shareholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision or combination. All calculations will be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of the Anti-Dilution Provisions, the number of shares of common stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of common stock (excluding any treasury shares) issued and outstanding.

Whenever the Conversion Price is adjusted pursuant to any Anti-Dilution Provision, we will promptly deliver to each holder of Series J Convertible Preferred Stock a notice setting forth the Conversion Price after such adjustment and setting forth a brief statement of the facts requiring such adjustment. Notwithstanding the foregoing in no event may the Conversion Price be less than the par value per share of Series J Convertible Preferred Stock.

Obligations Absolute. Subject to holder’s right to rescind a notice of conversion, our obligation to issue and deliver the shares of common stock upon conversion of Series J Convertible Preferred Stock in accordance with its terms are absolute and unconditional, irrespective of any action or inaction by a holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach

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or alleged breach by such holder or any other Person of any obligation to us or any violation or alleged violation of law by such holder or any other Person, and irrespective of any other circumstance which might otherwise limit our obligation to such holder in connection with the issuance of such shares of common stock. If we fail to deliver to a holder shares of common stock upon conversion by the Share Delivery Date applicable to such conversion, we shall pay to such holder, in cash, as liquidated damages and not as a penalty, for each \$250 of Stated Value of Series J Convertible Preferred Stock being converted, \$2.50 per Trading Day (increasing to \$5 per Trading Day on the third Trading Day after the Share Delivery Date and increasing to \$10 per Trading Day on the sixth Trading Day after the Share Delivery Date) for each Trading Day after the Share Delivery Date until such Conversion Shares are delivered or Holder rescinds such conversion.

Buy-In on Failure to Timely Deliver Certificates Upon Conversion. If we fail to deliver to a holder the applicable certificate or certificates or to effect a delivery via DWAC, as applicable, by the Share Delivery Date (other than a failure caused by incorrect or incomplete information provided by the holder to us), and if after such Share Delivery Date the holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the holder's brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by such holder of the Conversion Shares which the holder was entitled to receive upon the conversion relating to such Share Delivery Date (a "Buy-In"), then we are obligated to (A) pay in cash to the holder (in addition to any other remedies available to or elected by the holder) the amount by which (x) the holder's total purchase price (including any brokerage commissions) for the shares of common stock so purchased exceeds (y) the product of (1) the aggregate number of shares of common stock that such holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of the holder, either reissue (if surrendered) the shares of Series J Convertible Preferred Stock equal to the number of shares of Series J Convertible Preferred Stock submitted for conversion or deliver to the holder the number of shares of common stock that would have been issued if we had timely complied with our delivery requirements. For example, if a holder purchases shares of common stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted conversion of shares of Series J Convertible Preferred Stock with respect to which the actual sale price (including any brokerage commissions) giving rise to such purchase obligation was a total of \$10,000 under clause (A) of the immediately preceding sentence, we would be required to pay such holder \$1,000. The holder shall provide us written notice, within three Trading Days after the occurrence of a Buy-In, indicating the amounts payable to such holder in respect of such Buy-In together with applicable confirmations and other evidence reasonably requested by us. Nothing herein shall limit a holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect our failure to timely deliver certificates representing shares of common stock upon conversion of the shares of Series J Convertible Preferred Stock as required pursuant to the terms hereof; provided, however, that the holder shall not be entitled to both (i) require the reissuance of the shares of Series J Convertible Preferred Stock submitted for conversion for which such conversion was not timely honored and (ii) receive the number of shares of common stock that would have been issued if we had timely complied with applicable delivery requirements.

Reservation of Shares Issuable Upon Conversion. We have agreed that we will at all times reserve and keep available out of our authorized and unissued shares of common stock for the sole purpose of issuance upon conversion of the Series J Convertible Preferred Stock, free from preemptive rights or any other actual contingent purchase rights of Persons other than the holders of the Series J Convertible Preferred Stock, not less than such aggregate number of shares of the common stock as shall be issuable upon the conversion of all outstanding shares of Series J Convertible Preferred Stock. We have further agreed that all shares of common stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid, nonassessable and free and clear of all liens and other encumbrances.

Beneficial Ownership Limitation. Notwithstanding anything herein to the contrary, we shall not effect any conversion of the Series J Convertible Preferred Stock, and a Holder shall not have the right to convert any portion of the Series J Convertible Preferred Stock, to the extent that, after giving effect to the conversion set forth on the applicable Notice of Conversion, such 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 (such Persons, "Attribution Parties")) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of common stock beneficially owned by such Holder and its Affiliates and Attribution Parties shall include the number of shares of common stock

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issuable upon conversion of the Series J Convertible Preferred Stock with respect to which such determination is being made, but shall exclude the number of shares of common stock which are issuable upon (i) conversion of the remaining, unconverted Series J Convertible Preferred Stock beneficially owned by such Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other of our securities subject to a limitation on conversion or exercise analogous to the limitation contained herein (including, without limitation, the Series J Convertible Preferred Stock) beneficially owned by such Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this section, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. To the extent that the limitation contained in this section applies, the determination of whether the Series J Convertible Preferred Stock is convertible (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and of how many shares of Series J Convertible Preferred Stock are convertible shall be in the sole discretion of such Holder, and the submission of a Notice of Conversion shall be deemed to be such Holder's determination of whether the shares of Series J Convertible Preferred Stock may be converted (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and how many shares of the Series J Convertible Preferred Stock are convertible, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder will be deemed to represent to us each time it delivers a Notice of Conversion that such Notice of Conversion has not violated the restrictions set forth in this section and we shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this section, in determining the number of outstanding shares of common stock, a Holder may rely on the number of outstanding shares of common stock as stated in the most recent of the following: (i) our most recent periodic or annual report filed with the Commission, as the case may be, (ii) a more recent public announcement by us or (iii) a more recent written notice by us or the Transfer Agent setting forth the number of shares of common stock outstanding. Upon the written or oral request (which may be via email) of a Holder, we within one (1) Trading Day confirm orally and in writing to such Holder the number of shares of common stock then outstanding. In any case, the number of outstanding shares of common stock shall be determined after giving effect to the conversion or exercise of our securities, including the Series J Convertible Preferred Stock, by such Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of common stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any shares of Series J Convertible Preferred Stock, 9.99%) of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion of Series J Convertible Preferred Stock held by the applicable Holder. A Holder, upon notice to us, may increase or decrease the Beneficial Ownership Limitation provisions of this section applicable to its Series J Convertible Preferred Stock; provided, that the Beneficial Ownership Limitation shall not in any event exceed 9.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon conversion of this Series J Convertible Preferred Stock held by the Holder and the provisions of this section shall continue to apply. Any such increase will not be effective until the 61st day after such notice is delivered to us and shall only apply to such Holder and no other Holder. The Beneficial Ownership Limitation shall not be waived by us or the Holder and upon issuance of the Series J Convertible Preferred Stock by us, and the purchase thereof by the Holder, each of us and the Holder shall be deemed to acknowledge such limitation and to agree not to waive it. The provisions of this section shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this section to correct this section (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this subsection shall apply to a successor holder of Series J Convertible Preferred Stock.

Subsequent Rights Offerings. In addition to any anti-dilution adjustments described above, if at any time we grant, issue or sell any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of common stock or any class thereof (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of common stock acquirable upon complete conversion of such Holder's Series J Convertible Preferred Stock (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights,

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or, if no such record is taken, the date as of which the record holders of shares of common stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of common stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

Pro Rata Distributions. During such time as the Series J Convertible Preferred Stock is outstanding, if we declare or make any dividend or other distribution of our assets (or rights to acquire its assets) to holders of common stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of common stock acquirable upon complete conversion of the Series J Convertible Preferred Stock (without regard to any limitations on conversion hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of our common stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of common stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

Fundamental Transactions. In the event of a Fundamental Transaction and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, or the acquisition of more than 50% of our outstanding common stock, the holders of the Series J Convertible Preferred Stock will be entitled to receive upon conversion of the Series J Convertible Preferred Stock the kind and amount of securities, cash or other property that the holders would have received had they converted the Series J Convertible Preferred Stock immediately prior to such Fundamental Transaction (without regard to the Beneficial Ownership Limitation).

Mandatory Redemption. If any shares of Series J Convertible Preferred Stock are outstanding at the end of the three (3) year term, then we shall promptly redeem all of such outstanding shares of Series J Convertible Preferred Stock on a pro rata basis among all of the Holders of Series J Convertible Preferred Stock commencing on the third-year anniversary of the Closing Date at a price per Series J Convertible Preferred Share equal to the sum of (x) 100% of the Stated Value plus (y) all other amounts due in respect of the Series J Convertible Preferred Stock (if any). If on the Mandatory Redemption Date, Delaware law governing distributions to stockholders prevents the Company from redeeming all shares of Series J Convertible Preferred Stock to be redeemed, then the Corporation shall, provided there is no prohibition under Delaware law, redeem the Series J Convertible Preferred Stock by paying to the Holder the unpaid cash redemption payment in duly authorized, validly issued, fully paid and non-assessable shares of Common Stock equal in number to the quotient obtained by dividing such unpaid amount by the closing price of the Common Stock on the Trading Market on the Mandatory Redemption Date.

Limited Voting Rights. Holders of the Series J Convertible Preferred Stock will not have any voting rights, except as described below or as otherwise required by law.

In any matter in which the Series J Convertible Preferred Stock may vote (as expressly provided herein or as may be required by law), each share of Series J Convertible Preferred Stock will be entitled to one vote per share. So long as any shares of Series J Convertible Preferred Stock remain outstanding, the Company will not, without the consent or the affirmative vote of a majority of the outstanding shares of Series J Convertible Preferred Stock, given in person or by proxy, either in writing without a meeting or by vote at any meeting

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called for the purpose: (i) alter or change adversely the powers, preferences or rights given to the Series J Convertible Preferred Stock or alter or amend adversely the Certificate of Designations; (ii) increase the number of authorized shares of Series J Convertible Preferred Stock; or (iii) enter into any agreement with respect to any of the foregoing.

The rules and procedures for calling and conducting any meeting of the holders of the Series J Convertible Preferred Stock (including, without limitation, the fixing of a record date in connection therewith), the solicitation and use of proxies at such a meeting, the obtaining of written consents and any other aspect or matter with regard to such a meeting or such consents shall be governed by any rules the Board of Director (or a duly authorized committee of the Board of Directors), in its discretion, may adopt from time to time, which rules and procedures shall conform to the requirements of the Certificate of Incorporation, Bylaws, applicable law and any national securities exchange or other trading facility on which the Series J Convertible Preferred Stock may be listed or traded at the time.

Holders of the Series J Convertible Preferred Stock will not have any voting rights with respect to, and the consent of the holders of the Series J Convertible Preferred Stock is not required for, the taking of any corporate action, including any merger or consolidation involving the Company or a sale of all or substantially all of the Company's assets, regardless of the effect that such merger, consolidation or sale may have upon the powers, preferences, voting power or other rights or privileges of the Series J Convertible Preferred Stock, except as described above.

No Preemptive Rights. No holders of the Series J Convertible Preferred Stock will, as holders of Series J Convertible Preferred Stock, have any preemptive rights to purchase or subscribe for the common stock or any other security.

Exclusion of Other Rights. The shares of the Series J Convertible Preferred Stock do not have any voting powers, preferences or relative, participating, optional or other special rights, or qualifications, limitations or restrictions thereof, other than as set forth in the Certificate of Designations or in our Certificate of Incorporation.

Registration; Transfer. Pursuant to the terms of the Certificate of Designations, the Company is obligated to maintain an effective registration statement covering: (a) the issuance of shares of common stock issuable upon conversion of the Series J Convertible Preferred Stock and (b) the issuance of additional shares of Series J Convertible Preferred Stock pursuant to our obligation to pay PIK dividends, in each case, until such time as no Series J Convertible Preferred Stock (and no Warrants exercisable for shares of Series J Convertible Preferred Stock) remain outstanding, unless there is available an exemption from, or a transaction not subject to, the registration requirements of the Securities Act that covers the issuance of the Series J Convertible Preferred Stock and the shares of common stock issuable upon conversion of such shares of Series J Convertible Preferred Stock.

Book-Entry Procedures. DTC will act as securities depository for the Series J Convertible Preferred Stock offered hereunder. With respect to the Series J Convertible Preferred Stock offered hereunder, we will issue one or more fully registered global securities certificates in the name of DTC or DTC's nominee. These certificates will represent the total aggregate number of shares of Series J Convertible Preferred Stock. We will deposit these certificates with DTC or a custodian appointed by DTC. We will not issue certificates to you for the shares of Series J Convertible Preferred Stock that you purchase, unless DTC's services are discontinued as described below.

Title to book-entry interests in the Series J Convertible Preferred Stock will pass by book-entry registration of the transfer within the records of DTC in accordance with its procedures. Book-entry interests in the securities may be transferred within DTC in accordance with procedures established for these purposes by DTC. Each person owning a beneficial interest in shares of the Series J Convertible Preferred Stock must rely on the procedures of DTC and the participant through which such person owns its interest to exercise its rights as a holder of the Series J Convertible Preferred Stock. DTC has advised us that it is a limited-purpose trust company organized under the New York Banking Law, a member of the Federal Reserve System, a "clearing corporation" within the meaning of the New York Uniform Commercial Code and a "clearing agency" registered under the provisions of Section 17A of the Exchange Act. DTC holds securities that its participants ("Direct Participants") deposit with DTC. DTC also facilitates the settlement among Direct Participants of securities transactions, such as transfers and pledges in deposited securities through electronic computerized book-entry changes in Direct Participants' accounts, thereby eliminating the need for physical movement of securities certificates. Direct

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Participants include securities brokers and dealers, banks, trust companies, clearing corporations, and certain other organizations. Access to the DTC system is also available to others such as securities brokers and dealers, including the Placement Agent, banks and trust companies that clear through or maintain a custodial relationship with a Direct Participant, either directly or indirectly (“Indirect Participants”). The rules applicable to DTC and its Direct and Indirect Participants are on file with the SEC.

When you purchase shares of Series J Convertible Preferred Stock within the DTC system, the purchase must be by or through a Direct Participant. The Direct Participant will receive a credit for the Series J Convertible Preferred Stock on DTC’s records. You will be considered to be the “beneficial owner” of the Series J Convertible Preferred Stock. Your beneficial ownership interest will be recorded on the Direct Participants and Indirect Participants’ records, but DTC will have no knowledge of your individual ownership. DTC’s records reflect only the identity of the Direct Participants to whose accounts shares of Series J Convertible Preferred Stock are credited.

You will not receive written confirmation from DTC of your purchase. The Direct Participants or Indirect Participants through whom you purchased the Series J Convertible Preferred Stock should send you written confirmations providing details of your transactions, as well as periodic statements of your holdings. The Direct Participants and Indirect Participants are responsible for keeping an accurate account of the holdings of their customers like you.

Transfers of ownership interests held through Direct Participants and Indirect Participants will be accomplished by entries on the books of Direct Participants and Indirect Participants acting on behalf of the beneficial owners.

The laws of some states may require that specified purchasers of securities take physical delivery of shares of Series J Convertible Preferred Stock in definitive form. These laws may impair the ability to transfer beneficial interests in the global certificates representing the Series J Convertible Preferred Stock.

Conveyance of notices and other communications by DTC to Direct Participants, by Direct Participants to Indirect Participants, and by Direct Participants and Indirect Participants to beneficial owners will be governed by arrangements among them, subject to any statutory or regulatory requirements as may be in effect from time to time.

We understand that, under DTC’s existing practices, in the event that we request any action of the holders, or an owner of a beneficial interest in a global security, such as you, desires to take any action that a holder is entitled to take under our Certificate of Incorporation (including the Certificate of Designations designating the Series J Convertible Preferred Stock), DTC would authorize the Direct Participants holding the relevant shares to take such action, and those Direct Participants and any Indirect Participants would authorize beneficial owners owning through those Direct Participants and Indirect Participants to take such action or would otherwise act upon the instructions of beneficial owners owning through them.

Any redemption notices with respect to the Series J Convertible Preferred Stock will be sent to DTC or its nominee. If less than all of the outstanding shares of Series J Convertible Preferred Stock are being redeemed, DTC will reduce each Direct Participant’s holdings of shares of Series J Convertible Preferred Stock in accordance with its procedures.

In those instances where a vote is required, neither DTC nor its nominee will consent or vote with respect to the shares of Series J Convertible Preferred Stock. Under its usual procedures, DTC would mail an omnibus proxy to us as soon as possible after the record date. The omnibus proxy assigns DTC’s or its nominee’s consenting or voting rights to those Direct Participants whose accounts the shares of Series J Convertible Preferred Stock are credited to on the record date, which are identified in a listing attached to the omnibus proxy.

Dividends on the Series J Convertible Preferred Stock are made directly to DTC (or its successor, if applicable). DTC’s practice is to credit participants’ accounts on the relevant payment date in accordance with their respective holdings shown on DTC’s records unless DTC has reason to believe that it will not receive payment on that payment date.

Payments by Direct Participants and Indirect Participants to beneficial owners will be governed by standing instructions and customary practices, as is the case with securities held for the accounts of customers in bearer form or registered in “street name.” These payments will be the responsibility of the participant and not of DTC,

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us or any agent of ours. DTC may discontinue providing its services as securities depository with respect to the Series J Convertible Preferred Stock at any time by giving reasonable notice to us. Additionally, we may decide to discontinue the book-entry only system of transfers with respect to the Series J Convertible Preferred Stock. In that event, we will print and deliver certificates in fully registered form for the Series J Convertible Preferred Stock. If DTC notifies us that it is unwilling to continue as securities depository, or it is unable to continue or ceases to be a clearing agency registered under the Exchange Act and a successor depository is not appointed by us within 90 days after receiving such notice or becoming aware that DTC is no longer so registered, we will issue the Series J Convertible Preferred Stock in definitive form, at our expense, upon registration of transfer of, or in exchange for, such global security.

According to DTC, the foregoing information with respect to DTC has been provided to the financial community for informational purposes only and is not intended to serve as a representation, warranty or contract modification of any kind.

Global Clearance and Settlement Procedures. Initial settlement for the Series J Convertible Preferred Stock will be made in immediately available funds. Secondary market trading among DTC's participants occurs in the ordinary way in accordance with DTC's rules and will be settled in immediately available funds using DTC's Same-Day Funds Settlement System.

Direct Registration System. The Series J Convertible Preferred Stock will be registered in book-entry form through the Direct Registration System (the "DRS"). The DRS is a system administered by DTC pursuant to which the depository may register the ownership of uncertificated shares, which ownership shall be evidenced by periodic statements issued by the depository to the holders of shares of Series J Convertible Preferred Stock entitled thereto. This direct registration form of ownership allows investors to have securities registered in their names without requiring the issuance of a physical stock certificate, eliminates the need for you to safeguard and store certificates and permits the electronic transfer of securities to effect transactions without transferring physical certificates.

Description of Outstanding Warrants

As of December 31, 2023, there were warrants outstanding to purchase a total of 2,963,192 shares of our common stock, which expire between 2024 and 2028. Each of these warrants entitles the holder to purchase one share of common stock at prices ranging from \$3.30 to \$189,000 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%.

On June 19, 2023, we entered into a Supply and Collaboration Agreement (the "Supply Agreement") with DaVita Inc., a Delaware corporation ("DaVita"), pursuant to which DaVita will pilot the Aquadex ultrafiltration therapy system to treat adult patients with congestive heart failure and related conditions within select U.S. markets. The pilot period commenced on June 30, 2023 and extends through May 31, 2024 (the "Pilot"). The Company currently anticipates that the first patient to be treated with Aquadex in the Pilot will occur in the fourth quarter of 2023. Through the Pilot, ultrafiltration therapy using Aquadex will be offered at a combination of DaVita's customer hospital and outpatient center locations, with both companies collaborating on the roll-out of the therapy, clinician training, and patient support. At the conclusion of the pilot, DaVita has the option, in its sole discretion, to extend the Supply Agreement with the Company for continued provision of both inpatient and outpatient ultrafiltration services for up to 10 years ("Ultrafiltration Services Approval").

In conjunction with the Supply Agreement, the Company issued DaVita a warrant to purchase up to an aggregate of 1,289,081 shares of common stock of the Company, par value \$0.0001 per share, at an exercise price of \$3.2996 per share, provided that at no time can it be exercised for an amount of shares that would represent greater than 19.9% ownership in the Company (the "DaVita Warrant") subject to certain vesting milestones. The DaVita Warrant is expected to vest in four tranches as follows: (i) 25% upon the Company's

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receipt of the Ultrafiltration Services Approval; (ii) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within twelve months of Ultrafiltration Services Approval; (iii) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within twenty-four months of Ultrafiltration Services Approval; and (iv) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within thirty-six months of Ultrafiltration Services Approval.

October 2023 Offering Warrants

Exercisability. The October 2023 Warrants are exercisable at any time after their original issuance and at any time up to the date that is three years after the Closing Date. The October 2023 Warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, by payment in full in immediately available funds for the number of shares of Series J Convertible Preferred Stock purchased upon such exercise. The October 2023 Warrants do not include a cashless exercise feature. No fractional shares will be issued in connection with the exercise of an October 2023 Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the stated value of the Series J Convertible Preferred Stock. Accordingly, a holder of the October 2023 Warrants is entitled to exercise a number of October 2023 Warrants that would solely result in the holder receiving one or more whole shares of Series J Convertible Preferred Stock. If we fail to deliver to a holder the applicable certificate or certificates or to effect a delivery via DWAC, as applicable, (other than certain specified failures) and the holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the holder's brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by such holder of the Series J Convertible Preferred Stock which the holder anticipated receiving upon such exercise, then we shall (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of Series J Convertible Preferred Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of shares of Series J Convertible Preferred Stock that we were required to deliver to the holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Warrant and equivalent number of shares of Series J Convertible Preferred Stock for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the holder the number of shares of Series J Convertible Preferred Stock that would have been issued had we timely complied with its exercise and delivery obligations hereunder.

Exercise Limitation. A holder will not have the right to exercise any portion of the October 2023 Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the October 2023 Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

Exercise Price. The exercise price per October 2023 Warrant is \$7.50 to purchase one-half (0.5) of one shares of our Series J Convertible Preferred Stock, which is 50% of the public offering price per unit. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Adjustments. If, at any time while the October 2023 Warrants are outstanding: we (A) pay a stock dividend or otherwise make a distribution or distributions payable in shares of our Series J Convertible Preferred Stock (which, for avoidance of doubt, shall not include any shares of Series J Convertible Preferred Stock issued by us upon exercise of the October 2023 Warrants and shall not include any of the PIK dividends to be paid to holders of shares of Series J Convertible Preferred Stock); (B) subdivide outstanding shares of Series J Convertible Preferred Stock into a larger number of shares; (C) combine (including by way of a reverse stock split) outstanding shares of Series J Convertible Preferred Stock into a smaller number of shares or (D) issue, in the event of a reclassification of shares of the Series J Convertible Preferred Stock, any shares of our capital stock, which we refer to collectively as the "Anti-Dilution Provisions", then the number of shares issuable upon exercise of the Warrants shall be proportionately adjusted such that the aggregate exercise price of the October 2023 Warrants shall remain unchanged.

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Subsequent Rights Offerings. In addition to any adjustments pursuant to the paragraph above, if at any time that an October 2023 Warrant is outstanding we grant, issue or sell any preferred stock equivalents or rights to purchase shares, warrants, securities or other property pro rata to all of the record holders of the Series J Convertible Preferred Stock (the “Purchase Rights”), then the holder of the October 2023 Warrant will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of Series J Convertible Preferred Stock acquirable upon complete exercise of the October 2023 Warrant (without regard to any limitations on exercise hereof, including without limitation, the beneficial ownership limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Series J Convertible Preferred Stock are to be determined for the grant, issue or sale of such Purchase Rights.

Pro Rata Distributions. During such time as an October 2023 Warrant is outstanding, if we shall declare or make any dividend or other distribution of our assets (or rights to acquire our assets) to holders of shares of Series J Convertible Preferred Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, share or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (except to the extent an adjustment was already made pursuant to the second preceding paragraph), at any time after the issuance of the October 2023 Warrants, then, in each such case, the holder shall be entitled to participate in such distribution to the same extent that the holder would have participated therein if the holder had held the number of shares of Series J Convertible Preferred Stock acquirable upon complete exercise of the October 2023 Warrant immediately before the date of which a record is taken for such distribution, or, if no such record is taken, the date as of which the record holders of shares of Series J Convertible Preferred Stock are to be determined for the participation in such distribution. Any distribution or distributions to be paid to any holder of shares of Series J Convertible Preferred Stock arising as a result of our obligation to issue PIK dividends on the Series J Convertible Preferred Stock pursuant to the certificate of designations, shall be held in trust for the benefit of such holder of shares of Series J Convertible Preferred Stock holding the October 2023 Warrant at the time of exercise of the October 2023 Warrant, and paid to such holder only upon such exercise.

Transferability. Subject to applicable laws, the October 2023 Warrants may be offered for sale, sold, transferred or assigned without our consent.

No Listing. There is no established public trading market for, and we do not expect a market to develop for, the October 2023 Warrants. In addition, we do not intend to apply for listing of the October 2023 Warrants on any securities exchange or trading system, including Nasdaq. Without an active market, the liquidity of the October 2023 Warrants will be limited.

Warrant Agent; Global Certificate. The October 2023 Warrants will be issued in registered form under a warrant agency agreement between us and the Warrant Agent, Equiniti Trust Company, LLC. The October 2023 Warrants 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 (DTC) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Fundamental Transactions. In the event of a “fundamental transaction,” as defined in the October 2023 Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the October 2023 Warrants will be entitled to receive upon exercise of the October 2023 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the October 2023 Warrants immediately prior to such fundamental transaction.

Registration; Transfer. Pursuant to the terms of the October 2023 Warrants, we are obligated to maintain an effective registration statement covering the issuance of the shares of Series J Convertible Preferred Stock upon exercise of the October 2023 Warrants and the shares of common stock issuable upon conversion of such shares of Series J Convertible Preferred Stock until such time as no October 2023 Warrants remain outstanding, unless

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there is available an exemption from, or a transaction not subject to, the registration requirements of the Securities Act that covers the issuance of the Series J Convertible Preferred Stock and the shares of common stock issuable upon conversion of such shares of Series J Convertible Preferred Stock.

Rights as a Stockholder. Except as otherwise provided in the Warrants or by virtue of such holder's ownership of our common stock, the holder of a Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Warrant and converts the shares of Series J Convertible Preferred Stock received upon such exercise into shares of common stock.

Governing Law. The Warrants and the Warrant Agency Agreement are governed by New York law.

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

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

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

Delaware Law

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

- prior to that date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time

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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 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation or a direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, lease, mortgage, pledge transfer, or other disposition of the assets of the corporation or direct or indirect majority-owned a subsidiary of the corporation to or with the interested stockholder, which assets have an aggregate value equal to 10% or more of the fair value of the assets on a consolidated basis or the aggregate market value of the outstanding stock of the corporation;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or a direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or subsidiary to the interested stockholder;
- any transaction involving the corporation or direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or the subsidiary beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or direct or indirect majority-owned subsidiary of the corporation.

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

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

Choice of Forum

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

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

Limitation on Liability of Directors and Indemnification

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

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

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

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

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

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

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

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

Registration Rights

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

DESCRIPTION OF SECURITIES WE ARE OFFERING

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

The shares of common stock, pre-funded warrants, and common warrants that we are offering are immediately separable and will be issued separately.

Common Stock

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

Common Warrants

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

Duration, Exercise Price and Form. Each common warrant included in the units and pre-funded units will have an exercise price equal to \$0.49 per share (equal to 100% of the assumed public offering price per unit). The common warrants will be immediately exercisable and may be exercised until the five-year anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the common stock or the pre-funded warrants, as the case may be, and may be transferred separately immediately thereafter. The common warrants will be issued in electronic form.

Exercisability. The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise. A holder (together with its affiliates) may not exercise any portion of such holder’s warrants to the extent that the holder would own more than 4.99% of the outstanding common stock (or at the election of a holder prior to the date of issuance, 9.99%) immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder’s warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants. If, at the time of exercise there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of, the shares of common stock underlying the warrants, then the warrants may also be exercised, in whole or in part, at such time by means of a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

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

Fundamental Transactions. In the event of a fundamental transaction, as described in the common warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale,

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transfer or other disposition of all or substantially all of our properties or assets, our consolidation with or into another person, the acquisition of more than 50% of our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction, and the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the common warrants with the same effect as if such successor entity had been named in the common warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the common warrant following such fundamental transaction. In addition, in the event of a fundamental transaction, we or any successor entity will be required to purchase at a holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction (or, if later, the date of the public announcement of the applicable fundamental transaction), such holder's common warrants for cash in an amount equal to the value of the remaining unexercised portion of such holder's common warrants, determined in accordance with the Black Scholes option pricing model as more particularly set forth in the common warrants.

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

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

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

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

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

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

Pre-Funded Warrants

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

Duration, Exercise Price and Form. Each pre-funded unit will be sold in this offering at a purchase price equal to \$0.49 (equal to 100% of the assumed public offering price of each unit sold in this offering, minus \$0.0001). Each pre-funded warrant included in the pre-funded units offered hereby will have an initial exercise price per share equal to \$0.0001. The pre-funded warrants will be immediately exercisable and will not expire prior to exercise. The exercise price and number of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The pre-funded warrants will be issued in electronic form.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the

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issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act of 1933, as amended (the “Securities Act”), is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon notice from the holder to us, the holder may increase or decrease the beneficial ownership limitation in the holder’s pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice to us. If, at the time of exercise there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of, the shares of common stock underlying the pre-funded warrants, then the pre-funded warrants may also be exercised, in whole or in part, at such time by means of a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant.

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

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

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

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

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

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

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

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

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

PLAN OF DISTRIBUTION (CONFLICTS OF INTEREST)

We are offering on a reasonable best efforts basis up to 16,326,530 units, based on an assumed public offering price of \$0.49 per unit, which represents the closing price of our common stock on the Nasdaq Capital Market on January 26, 2024, for gross proceeds of up to approximately \$8,000,000 before deduction of placement agent fees and offering expenses. There is no minimum amount of proceeds that is a condition to closing of this offering. The actual amount of gross proceeds, if any, in this offering could vary substantially from the gross proceeds from the sale of the maximum amount of securities being offered in this prospectus.

Pursuant to a placement agency agreement, dated as of [•], 2024, we have engaged Lake Street Capital Markets, LLC (“Lake Street”) and Maxim Group LLC (“Maxim”) to act as the exclusive placement agents (the “placement agents”) to solicit offers to purchase the securities offered by this prospectus. The placement agents are not purchasing or selling any securities, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use their “reasonable best efforts” to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to the rights and remedies available to all investors in this offering under federal and state securities laws, the investors which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. The placement agents may engage one or more subagents or selected dealers in connection with this offering.

The placement agency agreement provides that the placement agents’ obligations are subject to conditions contained in the placement agency agreement.

The units will be offered at a fixed price and are expected to be issued in a single closing. There is no minimum number of units to be sold or minimum aggregate offering proceeds for this offering to close. We expect this offering to be completed not later than two business days following the commencement of this offering and we will deliver all securities issued in connection with this offering delivery versus payment (“DVP”)/receipt versus payment (“RVP”) upon our receipt of investor funds. Accordingly, neither we nor the placement agents have made any arrangements to place investor funds in an escrow account or trust account since the placement agents will not receive investor funds in connection with the sale of securities offered hereunder.

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

Placement Agent Fees, Commissions and Expenses

Upon the closing of this offering, we will pay the placement agents a cash transaction fee equal to 8.0% of the aggregate gross cash proceeds to us from the sale of the securities in the offering. In addition, we will reimburse the placement agents for certain of its out-of-pocket expenses incurred in connection with this offering, including the placement agents’ legal fees, and actual travel and reasonable out-of-pocket expenses, in an amount not to exceed \$100,000.

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us, assuming the sale of all units in this offering and no sale of any pre-funded units in this offering.

	Per Unit	Pre-Funded Units	Total
Public offering price	\$	\$	\$
Placement agents’ fees (8.0%)	\$	\$	\$
Proceeds to us (before expenses)	\$	\$	\$

We estimate that the total expenses of the offering, including registration and filing fees, printing fees and legal and accounting expenses, but excluding the placement agent fees, will be approximately \$373,000, all of which are payable by us. This figure includes, among other things, the placement agents’ expenses (including the legal fees, costs and expenses for the placement agents’ legal counsel) that we have agreed to reimburse.

Lock-Up Agreements

We have agreed with the placement agents not to, subject to certain exceptions, (i) offer, pledge, issue, sell, contract to sell, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock; (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of shares of our common stock; or (iii) file any registration statement with the SEC relating to this offering of any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, other than with respect to the registration of shares of our common stock to be issued under an equity incentive plan, without the prior written consent of the placement agents for a period of 90 days following the date of this prospectus (the “Lock-Up Period”). This consent may be given at any time. These restrictions on future issuances are subject to exceptions for (i) the filing by the Company of a registration statement on Form S-4 or a registration statement on Form S-8 or a successor form thereto with respect to securities pursuant to any stock option, stock bonus or other stock plan or arrangement or the proposal or authorization of any increase in the Company’s authorized capital stock, (ii) the issuance of securities sold in this offering, and the issuance of securities upon the conversion or exercise of securities sold in this offering, (iii) the issuance of shares of our common stock upon the exercise of outstanding options or warrants or the vesting of outstanding restricted stock units, (iv) the issuance of employee stock options not exercisable during the Lock-Up Period and the grant or forfeiture of restricted stock awards or restricted stock units pursuant to our equity incentive plans or other arrangements described in this prospectus or the documents incorporated by reference herein and (v) the issuance of securities issued pursuant to certain acquisitions or strategic transactions not primarily for the purpose of raising capital.

In addition, our directors and executive officers have entered into lock-up agreements with the placement agents. Under these agreements, these individuals have agreed, subject to certain specified exceptions, not to sell or transfer any shares of common stock or securities convertible into or exchangeable or exercisable for our shares of common stock during the Lock-Up Period, without first obtaining the written consent of the placement agents. Specifically, these individuals have agreed, in part, not to:

(1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or 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 (including without limitation, our common stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant), whether now owned or hereafter acquired (the “Undersigned’s Securities”);

(2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Undersigned’s Securities; whether any such transaction described in clause (1) or (2) above is to be settled by delivery of our common stock or such other securities, in cash or otherwise;

(3) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock; or

(4) publicly announce or disclose the intention to do any of the foregoing.

Right of First Refusal

There is an ongoing right of first refusal in favor of the placement agents, as set forth in that certain placement agency agreement by and among the Company, Lake Street and Maxim, dated October 12, 2023, which shall remain in place until April 17, 2024.

Tail

We have also agreed to pay the placement agents a tail fee equal to the cash compensation in this offering, if any investor, who was contacted or introduced to us by the placement agents during the term of their engagement who was not a prior investor in us, provides us with capital in any public or private offering or other financing or capital raising transaction during the 6-month period following consummation of this offering, subject to certain exceptions.

Indemnification

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

Regulation M

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

Determination of Offering Price and Warrant Exercise Price

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

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agents or an affiliate. Other than this prospectus, the information on any of the placement agents’ websites and any information contained in any other website maintained by the placement agents 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 of the placement agents, and should not be relied upon by investors. In connection with the offering, the placement agents or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

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

Conflicts of Interest and Other Relationships

Lake Street, a placement agent in this offering, has a “conflict of interest” under Rule 5121 of FINRA because one of our directors is the head of Life Science Investment Banking and a Managing Director at Lake Street. Accordingly, this offering will be made in compliance with the applicable provisions of Rule 5121. The rule requires that a “qualified independent underwriter” meeting certain standards participate in the preparation of the registration statement and prospectus and exercise the usual standards of due diligence with respect thereto. Maxim has agreed to act as a “qualified independent underwriter” within the meaning of Rule 5121 in connection with this offering. In its role as qualified independent underwriter, Maxim has participated in due diligence and the preparation of this prospectus and the registration statement of which this prospectus forms a part and has exercised the usual standards of due diligence with respect thereto.

The placement agents and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory,

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

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

In connection with the October 2023 Offering, we issued 150,000 units, with each unit consisting of one share of Series J Convertible Preferred Stock and one warrant to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock at an exercise price of \$15.00 per whole share. We received aggregate gross proceeds from the October 2023 Offering of approximately \$2.25 million, before deducting placement agent fees and commissions and other transaction expenses payable by us. Lake Street and Maxim acted as placement agents in the October 2023 Offering. In connection with the October 2023 Offering, we entered into a placement agency agreement, dated October 12, 2023, with Lake Street and Maxim, as placement agents, and on the closing of such offering on October 17, 2023, the placement agents received placement agent fees of 8.0% of the \$2.25 million of gross proceeds of the offering, as well as payment of certain expenses.

Listing

Our common stock is traded on Nasdaq under the symbol “NUWE.”

Transfer Agent and Registrar

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

Selling Restrictions

Notice to prospective investors in the United Kingdom

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

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

provided that no such offer of shares shall require the issuer or any placement agent to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any securities or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the placement agents and us that it is a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any securities being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the securities acquired

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by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any securities to the public other than their offer or resale in the United Kingdom to qualified investors as so defined or in circumstances in which the prior consent of the placement agents have been obtained to each such proposed offer or resale.

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

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

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

Notice to prospective investors in Canada

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

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

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

Notice to prospective investors in Australia

This prospectus:

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

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

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

Notice to prospective investors in the British Virgin Islands

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

Notice to prospective investors in Israel

In the State of Israel, this prospectus shall not be regarded as an offer to the public to purchase the securities under the Israeli Securities Law, 5728-1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728-1968, subject to certain conditions, or the Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728-1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for the securities to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors. Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728-1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728-1968 and the regulations promulgated thereunder in connection with the offer of the securities; (iv) that the securities that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728-1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728-1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

LEGAL MATTERS

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

EXPERTS

Baker Tilly US, LLP, our independent registered public accounting firm, has audited our consolidated financial statements as of and for the years ended December 31, 2022 and 2021 included in this prospectus, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file reports, proxy statements and other information with the SEC in accordance with the Exchange Act. Our reports, proxy statements and other information filed with the SEC are available free of charge to the public over the Internet at the SEC's website at <http://www.sec.gov>. These documents may also be accessed on our website at www.nuwellis.com. Information contained in, or accessible through, our website is not a part of this prospectus.

NUWELLIS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Nuwellis, Inc. and Subsidiary:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nuwellis, Inc. and Subsidiary (the “Company”) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders’ equity and cash flows, for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has recurring losses from operations, an accumulated deficit, expects to incur losses for the foreseeable future and needs additional working capital. These are the reasons that raise substantial doubt about their ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments.

The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

EVALUATION OF LONG-LIVED ASSETS FOR IMPAIRMENT

Critical Audit Matter Description

As described in Note 1 to the consolidated financial statements, the Company evaluates its long-lived assets, primarily property and equipment, for impairment whenever events and circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

The Company continues to report operating losses and negative cash flows from operations, both of which it considers to be indicators of potential impairment. Therefore, the Company evaluates its long-lived assets for potential impairment at each reporting period. The Company has concluded that its cash flows from the various long-lived assets are highly interrelated and, as a result, the Company consists of a single asset group.

As the Company expects to continue incurring losses in the foreseeable future, the undiscounted cash flow step was bypassed, and the Company proceeded to fair value the asset group. The Company has determined the fair value of the asset group using a composite approach. It is based on the expected cash flows associated with each of the components of the asset group. For the loaner units, the Company estimated future discounted cash flows expected from the units. For recently acquired assets within the asset group, primarily equipment, the Company determined the fair value based on the replacement cost. For the right of use asset, the Company estimated the value a market participant would pay to lease the asset for its highest and best use.

Considerable management judgment is necessary to estimate the fair value of the asset group; therefore, we considered the evaluation of long-lived assets for impairment as a critical audit matter.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- As part of our risk assessment procedures, we evaluated the design and implementation of the Company's controls over its process to evaluate the presence of indicators of potential impairment at the end of each reporting period and the determination of the asset group's fair value
- Testing the Company's conclusions regarding the interrelation of its cash flows in determining the asset grouping
- Testing the completeness, accuracy and relevance of the inputs and assumptions in determining the fair value of the asset grouping
- Testing a sample of the costs paid for acquisition of long-lived assets in the current year to corroborate the replacement cost of these assets
- Testing the discount rate used in the analysis.
- Testing the estimates of what a market participant would pay to lease the right-of-use asset for its highest and best use
- Testing the sensitivity of the significant inputs and assumptions to the determination of fair value

EVALUATION OF WARRANT LIABILITY

Critical Audit Matter Description

As described in Notes 5 and 6 to the consolidated financial statements, the Company issued 66,268 Common Stock Warrants which were classified as liabilities. Management determined the proper classification of the warrants by reviewing the terms and conditions of the issued warrants and applying the applicable accounting guidance, including Accounting Standards Codification (ASC) 480 Distinguishing Liabilities from Equity and ASC 815 Derivatives and Hedging. The Company determined the fair value of warrants at the date of issuance and year-end using a Monte Carlo simulation model.

We identified the assessment of the measurement of fair value of the common stock warrants as a critical audit matter. Specifically, there was a high degree of subjective auditor judgment, including the involvement of professionals with specialized skills and knowledge, due to the complex valuation methodology that incorporates several assumptions.

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How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- As part of our risk assessment procedures, we evaluated the design and implementation of the Company's controls over the Company's process to measure the fair value of its common stock warrant instrument.
- With the assistance of firm personnel having specialized skills and knowledge, we tested the model and methodology used to calculate the fair value of the common stock warrants including an independent re-calculation.
- Performed audit procedures surrounding management's assumptions utilized in the valuation model.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2017.

Minneapolis, Minnesota

March 3, 2023

NUWELLIS, INC. AND SUBSIDIARY
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 17,737	\$ 8,742
Marketable securities	569	15,463
Accounts receivable	1,406	750
Inventories, net	2,661	2,843
Other current assets	<u>396</u>	<u>328</u>
Total current assets	22,769	28,126
Property, plant and equipment, net	980	1,188
Operating lease right-of-use asset	903	1,082
Other assets	<u>21</u>	<u>21</u>
TOTAL ASSETS	\$ 24,673	\$ 30,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 2,245	\$ 1,414
Accrued compensation	2,161	1,664
Current portion of operating lease liability	196	167
Current portion of finance lease liability	28	26
Other current liabilities	58	36
Total current liabilities	4,688	3,307
Common stock warrant liability	6,868	—
Operating lease liability	760	956
Finance lease liability	—	28
Other long-term liability	<u>—</u>	<u>179</u>
Total liabilities	12,316	4,470
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Series I convertible preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 1,049,280 and none, issued and outstanding 1,049,280 and none, respectively	—	—
Preferred stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of December 31, 2022 and December 31, 2021, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 536,394 and 105,376, respectively	—	—
Additional paid-in capital	279,736	278,874
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(18)	(11)
Unrealized gain (loss) on marketable securities	56	(24)
Accumulated deficit	<u>(267,417)</u>	<u>(252,892)</u>
Total stockholders' equity	<u>12,357</u>	<u>25,947</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 24,673	\$ 30,417

See notes to the consolidated financial statements

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

	Year Ended December 31,	
	2022	2021
Net sales	\$ 8,543	\$ 7,921
Cost of goods sold	3,788	3,430
Gross profit	<u>4,755</u>	<u>4,491</u>
Operating expenses:		
Selling, general and administrative	17,584	19,039
Research and development	<u>4,342</u>	<u>4,978</u>
Total operating expenses	<u>21,926</u>	<u>24,017</u>
Loss from operations	(17,171)	(19,526)
Other income (expense), net		
Other income (expense), net	75	(19)
Financing expense	(9,247)	—
Change in fair value of warrant liability	11,827	—
Loss before income taxes	(14,516)	(19,545)
Income tax expense	(9)	(9)
Net loss	<u><u>\$(14,525)</u></u>	<u><u>\$(19,554)</u></u>
Basic and diluted loss per share	<u><u>\$ (83.55)</u></u>	<u><u>\$(285.36)</u></u>
Weighted average shares outstanding – basic and diluted	174	69
Other comprehensive loss:		
Unrealized gain (loss) on marketable securities	80	(24)
Unrealized foreign currency translation adjustment	<u>(7)</u>	<u>(4)</u>
Total comprehensive loss	<u><u>\$(14,452)</u></u>	<u><u>\$(19,582)</u></u>

See notes to the consolidated financial statements

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

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2020	27,360	\$—	\$249,663	\$ (7)	\$(233,338)	\$ 16,318
Net loss	—	—	—	—	(19,554)	(19,554)
Unrealized foreign currency translation adjustment	—	—	—	(4)	—	(4)
Unrealized loss on marketable securities	—	—	—	(24)	—	(24)
Stock-based compensation, net	—	—	1,314	—	—	1,314
Issuance of common stock, net	78,014	—	27,896	—	—	27,896
Exercise of warrants	<u>2</u>	<u>—</u>	<u>1</u>	<u>—</u>	<u>—</u>	<u>1</u>
Balance December 31, 2021	105,376	\$—	\$278,874	\$(35)	\$(252,892)	\$ 25,947
Net loss	—	—	—	—	(14,525)	(14,525)
Unrealized foreign currency translation adjustment	—	—	—	(7)	—	(7)
Unrealized gain on marketable securities	—	—	—	80	—	80
Stock-based compensation, net	—	—	862	—	—	862
Issuance of common stock, net	209,940	—	—	—	—	—
Conversion of preferred stock into common stock	<u>221,078</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Balance December 31, 2022	<u>536,394</u>	<u>\$—</u>	<u>\$279,736</u>	<u>\$ 38</u>	<u>\$(267,417)</u>	<u>\$ 12,357</u>

See notes to the consolidated financial statements

NUWELLIS, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows
(In thousands)

	For the years ended December 31,	
	2022	2021
Operating Activities		
Net loss	\$(14,525)	\$(19,554)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	372	488
Stock-based compensation expense, net	862	1,314
Change in fair value of warrant liability	(11,827)	—
Financing expense	9,247	—
Net realized and unrealized gains on marketable securities	124	13
Changes in operating assets and liabilities:		
Accounts receivable	(656)	155
Inventory	140	(143)
Other current assets	(68)	(91)
Other assets and liabilities	(96)	186
Accounts payable and accrued expenses	<u>1,278</u>	<u>(211)</u>
Net cash used in operations	(15,149)	(17,843)
Investing activities:		
Purchases of marketable securities	—	(18,850)
Proceeds from sales of marketable securities	14,850	3,350
Purchase of property and equipment	<u>(122)</u>	<u>(219)</u>
Net cash provided (used) in investing activities	14,728	(15,719)
Financing activities:		
Proceeds from public stock offerings, net	9,449	27,896
Proceeds from warrant exercises	—	1
Payments on finance lease liability	<u>(26)</u>	<u>(26)</u>
Net cash provided by financing activities	9,423	27,871
Effect of exchange rate changes on cash	(7)	(4)
Net increase in cash and cash equivalents	8,995	(5,695)
Cash and cash equivalents—beginning of year	8,742	14,437
Cash and cash equivalents—end of year	<u>\$ 17,737</u>	<u>\$ 8,742</u>
Supplemental schedule of non-cash activities		
Inventory transferred to property, plant and equipment	\$ 42	\$ 257
Operating right-of-use asset recorded as an operating lease liability	\$ —	\$ 901
Supplemental cash flow information		
Cash paid for income taxes	\$ 9	\$ 11

See notes to the consolidated financial statements

NUWELLIS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

Note 1—Nature of Business and Significant Accounting Policies***Nature of Business***

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

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

Going Concern

The Company’s financial statements have been prepared and presented on a basis assuming it continues as a going concern. During the years ended December 31, 2022 and 2021, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. As of December 31, 2022, the Company had an accumulated deficit of \$267.4 million, and it expects to incur losses for the immediate future. To date, the Company has been funded by equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it will ever operate profitably. These factors raise substantial doubt about the Company’s ability to continue as a going concern through at least twelve months from the report date.

The Company became a revenue-generating company after acquiring the Aquadex Business in August 2016. The Company expects to incur additional losses in the near-term as it grows the Aquadex Business, including investments in expanding its sales and marketing capabilities, purchasing inventory, manufacturing components, investing in clinical research and new product development, and complying with the requirements related to being a U.S. public company. To become and remain profitable, the Company must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require the Company to succeed in training personnel at hospitals and effectively and efficiently manufacturing, marketing, and distributing the Aquadex System and related components. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability.

During 2021 and through December 31, 2022, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately \$37.3 million after deducting the underwriting discounts and commissions and other costs associated with the offerings. See Note 4—Stockholders’ Equity for additional related disclosure. The Company will require additional funding to grow its Aquadex Business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions.

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

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Nuwellis, Inc. and its wholly owned subsidiary, Sunshine Heart Ireland Limited. All intercompany accounts and transactions between consolidated entities have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and term deposits with original maturities of three months or less. The carrying value of these instruments approximates fair value. The balances, at times, may exceed federally insured limits. The Company has not experienced any losses on its cash and cash equivalents.

Marketable securities

The Company's marketable securities typically consist of investment-grade, U.S. dollar-denominated fixed and floating-rate debt, which are classified as available-for-sale and included in current assets. Most marketable securities mature within twelve months from their date of purchase and generally are intended to fund current operations. Securities are valued based on market prices for similar assets using third party certified pricing sources. Available-for-sale securities are carried at fair value with unrealized gains and losses reported as a component of shareholders' equity in accumulated other comprehensive income (loss).

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis and impairment is indicated, it must be determined whether the impairment is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported as a component of shareholders' equity in accumulated other comprehensive gain (loss). There were no other than temporary unrealized losses as of December 31, 2022.

Accounts Receivable

Accounts receivables are unsecured, recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of collectability, historical experience, and management's evaluation of specific accounts, and it will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers' financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. To date the Company has not experienced any write-offs or significant deterioration in the aging of its accounts receivable, and therefore, no allowance for doubtful accounts was considered necessary as of December 31, 2022 or December 31, 2021. As of December 31, 2022, two customers represented 15% and 10% of the total accounts receivable balance. As of December 31, 2021, two customers represented 12% and 11% of the total accounts receivable balance.

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Inventories

Inventories are recorded at the lower of cost or net realizable value using the first-in, first-out method. Overhead is allocated to manufactured finished goods inventory based on the normal capacity of the Company's production facilities. Abnormal amounts of overhead, if any, are expensed as incurred. On a regular basis, the Company reviews its inventory and identifies that which is excess, slow moving, and obsolete by considering factors such as inventory levels and expected product life. A reserve is established for any identified excess, slow moving, and obsolete inventory through a charge to cost of goods sold. Inventories consisted of the following as of December 31:

<i>(Dollars in thousands)</i>	<u>2022</u>	<u>2021</u>
Finished Goods	\$ 993	\$1,527
Work in Process	204	276
Raw Materials	1,609	1,281
Inventory Reserves	(145)	(241)
Total	<u>\$2,661</u>	<u>\$2,843</u>

Other Current Assets

Other current assets represent prepayments and deposits made by the Company.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Depreciation is computed based upon the estimated useful life of the respective asset. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful life of the assets. Repairs and maintenance cost is expensed as incurred. The cost and accumulated depreciation of property, plant and equipment retired or otherwise disposed of is removed from the related accounts, and any residual values are charged to expense. Depreciation expense has been calculated using the following estimated useful lives:

Production Equipment	3-7 years
Office Furniture and Fixtures	3-5 years
Computer Software and Equipment	3-4 years
Loaners and demo equipment	1-5 years
Leasehold improvements	3-5 years

Depreciation expense was \$372,000 and \$488,000 for the years ended December 31, 2022 and 2021, respectively.

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

The Company continues to report operating losses and negative cash flows from operations, both of which it considers to be indicators of potential impairment. Therefore, the Company evaluates its long-lived assets for potential impairment at each reporting period. The Company has concluded that its cash flows from the various long-lived assets are highly interrelated and, as a result, the Company consists of a single asset group. As the Company expects to continue incurring losses in the foreseeable future, the undiscounted cash flow step was bypassed, and the Company proceeded to fair value the asset group. The Company has determined the fair value of the asset group using a combination of expected discounted cash flows and other fair value indicators related to the asset grouping.

There have been no impairment losses recognized for the years ended December 31, 2022 or 2021.

Accounts Payable and Accrued Liabilities

Accrued liabilities includes amounts accrued but not invoiced related to payments owed for licensing agreements, director fees, and others.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers*. Accordingly, the Company recognizes revenue when its customers obtain control of its products or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. See Note 2 – Revenue Recognition, for additional disclosures. For the year ended December 31, 2022, one customer represented 12.5% of net sales. For the years ended December 31, 2021, two customers represented 12.3% and 10.7% of net sales.

Foreign Currency Translation

Sales and expenses denominated in foreign currencies are translated at average exchange rates in effect throughout the year. Assets and liabilities of foreign operations are translated at period-end exchange rates with the impacts of foreign currency translation recorded in cumulative translation adjustment, a component of accumulated other comprehensive income. Foreign currency transactions gains and losses are included in other expense, net in the consolidated statements of operations and other comprehensive loss.

Stock-Based Compensation

The Company recognizes all share-based payments to employees, directors, and consultants, including grants of stock options and common stock awards, in the consolidated statement of operations and comprehensive loss as an operating expense based on their fair values as established at the grant date. Equity instruments issued to non-employees include common stock awards or warrants to purchase shares of our common stock. These common stock awards or warrants are either fully vested and exercisable at the date of grant or vest over a certain period during which services are provided. The Company expenses the fair market value of fully vested awards at the time of grant, and of unvested awards over the period in which the related services are received.

The Company computes the estimated fair values of stock options using the Black-Scholes option pricing model. Market price at the date of grant is used to calculate the fair value of common stock awards.

Stock-based compensation expense is based on awards ultimately expected to vest and is reduced for forfeitures. See Note 5—Stock-Based Compensation, for further information regarding the assumptions used to calculate the fair value of stock-based compensation.

Income Taxes

Deferred income taxes are provided on a liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences, which are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Loss per share

Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders for the year ended December 31, 2021, includes a deemed dividend of \$75,000 that resulted from the change in the exercise price of warrants as a result of the March 2021 and September 2021 public offerings. (see Note 4 — Stockholders’ Equity).

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

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

	December 31,	
	2022	2021
Stock options	10,485	7,481
Warrants to purchase common stock	679,244	16,299
Series F convertible preferred stock	5,080	50,800
Series I convertible preferred stock	10,493	—
Total	<u>705,302</u>	<u>74,580</u>

The following table reconciles reported net loss with reported net loss per share for the years ended December 31:

<i>(in thousands, except per share amounts)</i>	2022	2021
Net loss	<u>\$(14,525)</u>	<u>\$(19,545)</u>
Deemed dividend to preferred stockholders (see Note 4)	—	(75)
Net loss after deemed dividend	(14,525)	(19,620)
Weighted average shares outstanding	174	69
Basic and diluted loss per share	<u>\$ (83.55)</u>	<u>\$(285.36)</u>

Research and Development

Research and development (R&D) costs include activities related to development, design, and testing improvements of the Aquadex System and potential related new products. These R&D costs also include expenses related to clinical research that the Company may sponsor or conduct to enhance understanding of the product and its use. R&D costs are expensed as incurred.

Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update (ASU) 2016-13, “Financial Instruments – Credit Losses.” This ASU added a new impairment model (known as the current expected credit loss (“CECL”) model) that is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes an allowance its estimate of expected credit losses. The CECL model applies to most debt instruments, trade receivables, lease receivables, financial guarantee contracts, and other loan commitments. The CECL model does not have a minimum threshold for recognition of impairment losses, and entities will need to measure expected credit losses on assets that have a low risk of loss. As a smaller reporting company pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended, these changes become effective for the Company on January 1, 2023. Management has evaluated the potential impact of these changes on the consolidated financial statements of the Company and does not anticipate it will have any impact to the Company’s consolidated financial statements.

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

Note 2 – Revenue Recognition

Net Sales

The Company sells its products in the United States primarily through a direct salesforce. Customers who purchase the Company’s products include hospitals and clinics throughout the United States. In countries outside

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the United States, the Company sells its products through a limited number of specialty healthcare distributors in Austria, Brazil, Colombia, the Czech Republic, Germany, Greece, Hong Kong, India, Israel, Italy, Panama, Romania, Singapore, Slovakia, Spain, Switzerland, Thailand, United Arab Emirates, and the United Kingdom. These distributors resell the Company's products to hospitals and clinics in their respective geographies.

Revenue from product sales is recognized when the customer or distributor obtains control of the product, which occurs at a point in time, most frequently upon shipment of the product or receipt of the product, depending on shipment terms. The Company's standard shipping terms are FOB shipping point unless the customer requests that control and title to the inventory transfer upon delivery. Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when the Company satisfies its performance obligations under the contract. The majority of the Company's contracts have a single performance obligation and are short term in nature. The Company has entered into extended service plans with customers, which are recognized over time. This revenue represents less than 1% of net sales for each of the years ended December 31, 2022 and 2021. The unfulfilled performance obligations related to these extended service plans are included in deferred revenue, which is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

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

Product Returns: The Company offers customers a limited right of return for its product in case of non-conformity or performance issues. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own historical sales and returns information. The Company has not received any returns to date and believes that future returns of its products will be minimal. Therefore, revenue recognized is not currently impacted by variable consideration related to product returns.

Note 3—Property, Plant and Equipment

Property, plant and equipment were as follows:

<i>(in thousands)</i>	December 31, 2022	December 31, 2021
Production Equipment	\$ 1,360	\$ 1,321
Loaners and Demo Equipment	1,444	1,364
Computer Software and Equipment	719	714
Office Furniture & Fixtures	375	364
Leasehold Improvements	<u>253</u>	<u>245</u>
Total	4,151	4,008
Accumulated Depreciation	<u>(3,171)</u>	<u>(2,820)</u>
	<u>\$ 980</u>	<u>\$ 1,188</u>

Note 4—Stockholders' Equity

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

The offering was comprised of Series F convertible preferred stock, convertible into shares of the Company's common stock at a conversion price of \$189,000 per share. Each share of Series F convertible preferred stock was accompanied by a Series 1 warrant, which was to expire on the first anniversary of its

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

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

As of December 31, 2022, and December 31, 2021, 127 shares of the Series F convertible preferred stock remained outstanding.

Series H Convertible Preferred Stock and January 2020 Offering: On January 28, 2020, the Company closed on an underwritten public offering of common stock, Series H convertible preferred stock, and warrants to purchase shares of common stock for gross proceeds of \$9.7 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants ("January 2020 Offering"). Net proceeds totaled approximately \$8.6 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The Series H convertible preferred stock included a beneficial conversion amount of \$1.6 million, representing the intrinsic value of the shares at the time of issuance, and \$0.2 million of down-round protection in connection with the re-pricing of the warrants following the March 2020 offering described below. This amount is reflected as an increase to the loss per share allocable to common stockholders in the year ended December 31, 2020.

The January 2020 Offering was comprised of 2,015 shares of common stock priced at \$1,650 per share and 115,173 shares of Series H convertible preferred stock, convertible into common stock at \$1,650 per share, including the full exercise of the over-allotment option. Each share of Series H convertible preferred stock and each share of common stock was accompanied by a warrant to purchase common stock. The warrants are exercisable into 5,855 shares of common stock. The conversion price of the preferred stock issued in the transaction is fixed and does not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock) or liquidation preference, and, subject to limited exceptions, has no voting rights. The securities comprising the units are immediately separable and were issued separately. The warrants were exercisable beginning on the closing date and expire on the fifth anniversary of the closing date and had an initial exercise price per share equal to \$1,650 per share, subject to appropriate adjustment in the event of subsequent equity sales of common stock or securities convertible into common stock for an exercise price per share less than the exercise price per share of the warrants then in effect (but in no event lower than 10% of the applicable unit offering price), or in the event of recapitalization events,

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stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. Effective March 23, 2020, the exercise price of these warrants was reduced from \$1,650 to \$900, the per share price to the public in the March 2020 offering, described below.

As of December 31, 2020, all 115,173 shares of the Series H convertible preferred stock had been converted into common stock and none remained outstanding. As of December 31, 2020, warrants to purchase 4,552 shares of common stock had been exercised for total cash proceeds of \$4.1 million.

March 2020 Offering: On March 23, 2020, the Company closed on a registered direct offering of 1,387 shares of its common stock at a price to the public of \$900 per share, for gross proceeds of approximately \$1.2 million, or \$1.0 million net proceeds, after deducting commissions and offering expenses. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 1,387 shares of the Company's common stock. The warrants to purchase up to 1,387 shares of common stock have an exercise price of \$1,118 per share, were exercisable six months from the date of issuance, and will expire five and a half years from the date of issuance.

April 2020 Offering: On April 1, 2020, the Company closed on a registered direct offering of 1,710 shares of its common stock at a price to the public of \$1,302 per share, for gross proceeds of approximately \$2.2 million, prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 855 shares of the Company's common stock. The warrants have an exercise price of \$1,115 per share, were exercisable immediately, and will expire five and a half years from the date of issuance.

May 2020 Offering: On May 5, 2020, the Company closed on a registered direct offering of 1,199 shares of its common stock at a price to the public of \$1,418 per share, for gross proceeds of approximately \$1.7 million, prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 600 shares of the Company's common stock. The warrants have an exercise price of \$1,230 per share, were exercisable immediately, and will expire five and a half years from the date of issuance.

August 2020 Offering: On August 21, 2020, the Company closed on an underwritten public offering of common stock and warrants to purchase shares of common stock for gross proceeds of approximately \$14.4 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants ("August 2020 Offering"). Net proceeds totaled approximately \$13.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The August 2020 Offering was comprised of 10,647 shares of common stock priced at \$1,350 per share. Each share of common stock was accompanied by a warrant to purchase common stock. The warrants are exercisable into 10,647 shares of common stock. The securities comprising the units are immediately separable and were issued separately. The warrants were exercisable beginning on the effective date of our stockholders' approval of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, which occurred on October 6, 2020, and will expire on the five-year anniversary of the closing date.

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

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

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

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

October 2022 Offering: On October 18, 2022, the Company closed on an underwritten public offering of 209,940 shares of common stock and 23,157,124 shares of Series I convertible preferred stock, for gross proceeds of approximately \$11.0 million (the “October 2022 Offering”). Net proceeds totaled approximately \$9.4 million after deducting underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their overallotment option.

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

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

On December 8, 2022, following a special meeting of stockholders, the Company’s board of directors approved a one-for-one hundred reverse stock split of the Company’s issued and outstanding shares of common stock (the “*Reverse Stock Split*”). On December 9, 2022, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation (the “*Certificate of Amendment*”) to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on December 9, 2022, and the Company’s common stock began trading on a split-adjusted basis when the market opened on December 12, 2022. The conversion price of the preferred stock issued in the transaction was fixed and does not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock) or liquidation preference and, subject to limited exceptions, has no voting rights. The securities comprising the units are immediately separable and were issued separately.

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

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

Market-Based Warrants: On May 30, 2019, the Company granted a market-based warrant to a consultant in exchange for investor relations services. The warrant represents the right to acquire up to 33 shares of the Company’s common stock at an exercise price of \$9,540 per share, the closing stock price of the Company’s common shares on May 30, 2019. The warrant is subject to a vesting schedule based on the Company achieving certain market stock prices within a specified period of time. The warrant expires on May 30, 2024. None of these warrants had vested as of December 31, 2022.

Reverse Stock Split: On December 5, 2022, the Company’s stockholders approved the Company’s management to execute a reverse split of its outstanding common stock at a ratio in the range of 1-for-50 to 1-for-100 and, on December 8, 2022, the Company’s board of directors approved a 1-for-100 reverse split of the Company’s outstanding common stock that became effective after trading on December 9, 2022. This reverse

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stock split did not change the par value of the Company's common stock or the number of common or preferred shares authorized by the Company's Fourth Amended and Restated Certificate of Incorporation, as amended. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

Note 5— Stock-Based Compensation***Stock Options and Restricted Stock Awards***

The Company has various share-based compensation plans, including the Third Amended and Restated 2017 Equity Incentive Plan, the 2013 Non-Employee Directors' Equity Incentive Plan and the 2021 Inducement Plan (collectively, the "**Plans**"). The Plans are designed to assist in attracting, motivating, and retaining employees and directors and to recognize the importance of employees to the long-term performance and success of the Company. The Company has also granted stock options to certain non-employees outside of the Plans.

The Company recognized stock-based compensation expense related to grants of stock options and common stock awards to employees, directors and consultants of \$862,000 and \$1.3 million during the years ended December 31, 2022 and 2021, respectively. The following table summarizes the stock-based compensation expense that was recognized in the consolidated statements of operations for the years ended December 31,

(Dollars in thousands)	2022	2021
Selling, general and administrative	\$784	\$1,171
Research and development	78	143
Total	\$862	\$1,314

The majority of the common stock awards and options to purchase common stock vest on the anniversary of the date of grant, which ranges from one to four years. Stock-based compensation expense related to these awards is recognized on a straight-line basis over the related vesting term in most cases, which generally is the service period. It is the Company's policy to issue new shares upon the exercise of options.

Stock Options: The following is a summary of the Plans' stock option activity during the years ended December 31:

	2022		2021	
	Options Outstanding	Weighted Average Exercise Price	Options Outstanding	Weighted Average Exercise Price
Beginning Balance	7,481	\$656.05	144	\$40,534.00
Granted	5,833	83.96	9,081	444.83
Exercised	—	—	—	—
Forfeited/expired	(2,829)	410.34	(1,744)	2,332.06
Outstanding at December 31	10,485	\$404.08	7,481	\$ 656.05
Vested at December 31	3,531	\$727.26	409	\$ 4,218.40

For options outstanding and vested at December 31, 2022 and 2021, the weighted average remaining contractual life was 8.79 years and 8.63 years, respectively. There were no option exercises in 2022 or 2021. The total fair value of options that vested in 2022 and 2021 was \$1.1 million, and \$0.7 million, respectively, at the fair value of the options as of the date of grant.

Valuation Assumptions: The fair value of each stock option is estimated at the grant date using the Black-Scholes option pricing model. The fair value of stock options under the Black-Scholes option pricing model requires management to make assumptions regarding projected employee stock option exercise behaviors, risk-free interest rates, volatility of the Company's stock price, and expected dividends.

The Company has not historically paid cash dividends to its stockholders and currently does not anticipate paying any cash dividends in the foreseeable future. As a result, the Company has assumed a dividend yield of

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0%. The risk-free interest rate is based upon the rates of U.S. Treasury bills with a term that approximates the expected life of the option. Since the Company has limited historical exercise data to reasonably estimate the expected life of its option awards, the expected life is calculated using a simplified method. Expected volatility is based on historical volatility of the Company's stock.

The following table provides the weighted average assumptions used in the Black-Scholes option pricing model for the years ended December 31:

	2022	2021
Expected dividend yield	0%	0%
Risk-free interest rate	2.13%	1.19%
Expected volatility	132.48%	131.03%
Expected life (in years)	6.15	6.21

The weighted-average fair value of stock options granted in 2022 and 2021 was \$76.05 and \$396.17, respectively. As of December 31, 2022, the total compensation cost related to all non-vested stock option awards not yet recognized was approximately \$1.3 million and is expected to be recognized over the remaining weighted-average life of 2.54 years.

Warrants: Warrants to purchase 679,244 and 16,299 shares of common stock were outstanding on December 31, 2022 and 2021, respectively. As of December 31, 2022, warrants outstanding were exercisable at prices ranging from \$25 to \$189,000 per share and are exercisable over a period ranging from immediately to 5.8 years.

Note 6—Fair Value of Financial Instruments

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

Pursuant to the requirements of ASC Topic 820 "*Fair Value Measurement*," the Company's financial assets and liabilities measured at fair value on a recurring basis are classified and disclosed in one of the following three categories:

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

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

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

(Dollars in thousands)	2022		2021	
	Fair Value	Level 1	Fair Value	Level 1
Marketable securities	<u>\$569</u>	<u>\$569</u>	<u>\$15,463</u>	<u>\$15,463</u>

The fair value of the Company's common stock warrant liability related to the investor warrants issued in the October 2022 public offering, was calculated using a Monte Carlo valuation model and was classified as Level 3 in the fair value hierarchy.

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

(in thousands)

October 18, 2022 warrant issuance	\$ 18,695
Change in fair value	(11,827)
Ending balance December 31, 2022	\$ 6,868

Fair values were calculated using the following assumptions:

	<u>Oct. 18, 2022</u>	<u>Dec. 31, 2022</u>
Risk-free interest rates, adjusted for continuous compounding	4.16%	3.97%
Term (years)	6.18	6.11
Expected volatility	141.5%	145.3%
Dates and probability of future equity raises	various	various

A significant change in the inputs used for the Monte Carlo and Black Scholes valuation models, such as the expected volatility, risk-free interest rate, or probability of future equity financings, in isolation, would result in significantly higher or lower fair value measurements. In combination, changes in these inputs could result in a significantly higher or lower fair value measurement if the input changes were to be aligned or could result in a minimally higher or lower fair value measurement if the input changes were of a compensating nature.

Note 7—Income Taxes

Domestic and foreign income (loss) before income taxes consists of the following for the years ended December 31:

(in thousands)	<u>2022</u>	<u>2021</u>
Domestic	\$(14,551)	\$(19,582)
Foreign	35	37
Loss before income taxes	<u>\$(14,516)</u>	<u>\$(19,545)</u>

The components of income tax expense consist of the following for the years ended December 31:

(in thousands)	<u>2022</u>	<u>2021</u>
Current:		
United States and state	\$—	\$—
Foreign, net	(9)	(9)
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax expense	<u>\$(9)</u>	<u>\$(9)</u>

Actual income tax expense differs from statutory federal income tax expense as follows for the years ended December 31:

(in thousands)	<u>2022</u>	<u>2021</u>
Statutory federal income tax benefit	\$ 3,048	\$ 4,109
State tax benefit, net of federal taxes	783	560
Foreign tax	(1)	(1)
Nondeductible/nontaxable items	548	(220)
Other	(41)	406
Valuation allowance (increase) decrease	(4,346)	(4,863)
Total income tax expense	<u>\$(9)</u>	<u>\$(9)</u>

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Deferred taxes consist of the following as of December 31:

<i>(in thousands)</i>	2022	2021
Deferred tax assets:		
Noncurrent:		
Accrued leave	\$ 397	\$ 59
Stock based compensation	360	368
Net operating loss carryforward	45,405	42,363
Other	42	131
Intangibles	1,786	723
R&D credit carryforward	531	531
Total deferred tax assets	48,521	44,175
Less: valuation allowance	(48,521)	(44,175)
Total	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2022, the Company had federal net operating loss (“NOL”) carryforwards of approximately \$198.1 million and state NOL carryforwards of \$53.8 million. Approximately \$120.1 million of federal NOL carryforwards will expire between 2024 and 2038. Pursuant to the Tax Cuts and Jobs Act of 2017, NOLs generated after 2017 of approximately \$78.0 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, 2020, the Company no longer has tax loss carryforwards in the Commonwealth of Australia due to the dissolution of its Australian subsidiary in November 2020.

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of the deferred tax assets. The Company has established a valuation allowance for U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying consolidated financial statements. For the years ended December 31, 2022, and 2021, the valuation allowance increased by \$4.3 million and \$4.9 million, respectively. The current year increase was primarily due to the federal and state net operating losses generated.

During 2022 and 2021, the Company believes it experienced an ownership change as defined in Section 382 of the Internal Revenue Code, which will limit the ability to utilize the Company’s net operating losses (NOLs). The Company may have experienced additional ownership changes in earlier years further limiting the NOL carryforwards that may be utilized. The Company has not yet completed a formal Section 382 analysis. The general limitation rules allow the Company to utilize its NOLs subject to an annual limitation that is determined by multiplying the federal long-term tax-exempt rate by the Company’s value immediately before the ownership change.

The accounting guidance related to uncertain tax positions prescribes a recognition threshold and measurement attribute for recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company had no material uncertain tax positions as of December 31, 2022 or 2021.

The Company recognizes interest and penalties on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. At December 31, 2022 and 2021, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The tax years ended December 31, 2019 through December 31, 2022 remain open to examination by the Internal Revenue Service and by the various states where the Company is subject to taxation. Additionally, the returns of the Company’s Australian (through November 2020) and Irish subsidiaries are subject to examination by tax authorities of those jurisdictions for the tax years ended and subsequent to June 30, 2017 and December 31, 2017, respectively.

Note 8—Operating Leases

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

The cost components of the Company's operating lease were as follows for the year ended December 31:

(in thousands)	2022	2021
Operating lease cost	\$238	\$219
Variable lease cost	127	123
Total	<u>\$365</u>	<u>\$342</u>

Variable lease costs consist primarily of taxes, insurance, and common area or other maintenance costs for our leased office and manufacturing space.

Maturities of our lease liability for the Company's operating lease are as follows as of December 31:

(in thousands)	2022
2023	\$ 249
2024	257
2025	264
2026	272
2027	69
Total lease payments	<u>1,111</u>
Less: Interest	<u>(155)</u>
Present value of lease liability	<u>\$ 956</u>

As of December 31, 2022, and 2021, the remaining lease terms were 4.25 and 5.25 years, respectively, and discount rates were 6.25% and 7.5% respectively. For the years ended December 31, 2022, and 2021, the operating cash outflows from the Company's operating lease for office and manufacturing space were \$238,000 and \$219,000, respectively.

Note 9—Finance Lease Liability

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

Note 10—Commitments and Contingencies***Employee Retirement Plan***

The Company has a 401(k) plan that provides a retirement benefit to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations, with the Company matching a portion of the employees' contributions at the discretion of the Company. Matching contributions totaled \$185,000 and \$255,000 for the years ended December 31, 2022 and 2021, respectively.

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Non-refundable Technology License Fee

On June 24, 2021, the Company entered into a research and development collaboration agreement with Koronis Biomedical Corporation (KBT) to design and develop an integrated continuous renal replacement therapy device. This agreement became effective on August 5, 2021, when KBT received approval of a \$1.7 million grant from the National Institutes of Health (NIH) to support this project. As part of this agreement, the Company will pay KBT a non-refundable technology license fee of \$428,160, payable in twelve equal monthly installments commencing on June 1, 2022. The Company has recorded a liability for the non-refundable technology license fee, with \$178,400 included in Current Accounts Payable at December 31, 2022. The full amount of \$428,160 was expensed and included in the Research and Development Expense line for the year ended December 31, 2021.

Note 11—Related Party Transactions

There were no related party transactions requiring disclosure during the year ended December 31, 2022 and 2021.

Note 12—Segment and Geographic Information

The Company has one reportable segment, fluid management.

At December 31, 2022 and 2021, long-lived assets were located primarily in the United States.

Note 13—Revision and Immaterial Correction of an Error in Previously Issued Financial Statements

The Company identified an error related to the classification and disclosures of marketable securities in our consolidated financial statements as of and for the year ended December 31, 2021 as reported on Form 10-K. In our December 31, 2021 consolidated financial statements, we incorrectly classified short term marketable securities as a cash and cash equivalents on the consolidated balance sheet. There was no change to the total current assets on the consolidated balance sheet. Additionally, we recorded an unrealized gain in other income on the consolidated statement of operations. This unrealized gain should have been recorded as accumulated other comprehensive income in the consolidated statement of operations and comprehensive loss and the consolidated statements of stockholders' equity. This correction also impacts the consolidated statement of cash flows, as the purchase of these securities and redemption of these securities would be shown in the investing activities section. In accordance with ASC 250, *Accounting Changes and Error Corrections*, we evaluated the materiality of the errors from quantitative and qualitative perspectives and concluded that the errors were immaterial to the Company's 2021 audited financial statements. Since these revisions were not material to any prior period financial statements, no amendments to previously filed financial statements are required. Consequently, the Company has corrected these immaterial errors by revising the December 31, 2021 consolidated financial statements presented herein.

The tables below present the effect of the financial statement adjustments related to the revision discussed above of the Company's previously reported financial statements as of and for the periods ended December 31, 2021.

The effect of the immaterial correction of an error on our previously filed audited consolidated financial statements as of December 31, 2021 and for the year then ended is as follows:

<i>(in thousands)</i>	December 31, 2021		
	As reported	Adjustment	As revised
<i>Consolidated Balance Sheet</i>			
Cash and cash equivalents	\$24,205	\$(15,463)	\$ 8,742
Marketable securities	—	15,463	15,463
Total Current Assets	28,126	—	28,126

Consolidated Statement of Operations and Comprehensive Loss

<i>(in thousands)</i>	As reported	Adjustment	As revised
Other income (expense)	(43)	24	(19)
Unrealized gains (losses) on marketable securities	—	(24)	(24)
	(43)	—	(43)

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Consolidated Statement of Cash Flows

<i>(in thousands)</i>	As reported	Adjustment	As revised
Net realized and unrealized gains on marketable securities	<u>—</u>	<u>13</u>	<u>13</u>
Net cash provided in operations	—	13	13
Purchases of marketable securities	<u>—</u>	<u>(18,850)</u>	<u>(18,850)</u>
Proceeds from sales of marketable securities	<u>—</u>	<u>3,350</u>	<u>3,350</u>
Net cash used in investing activities	—	(15,500)	(15,500)
Beginning cash and cash equivalents	14,437	—	14,437
Ending cash and cash equivalents	\$24,205	\$(15,463)	\$ 8,742

Note 14—Subsequent Events

On January 4, 2023, shareholder approval was secured by the Company for the issuance of the common stock warrants issued in conjunction with the Company’s October 2022 financing. During 2023, through February 24, 2023, there were 660,046 common stock warrants which had converted into 660,046 shares of common stock at a \$0 exercise price with no proceeds received by the Company.

At-The-Market Offering

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

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

	September 30, 2023	December 31, 2022
ASSETS	(unaudited)	
Current assets		
Cash and cash equivalents	\$ 4,930	\$ 17,737
Marketable securities	—	569
Accounts receivable	1,425	1,406
Inventories, net	2,336	2,661
Other current assets	947	396
Total current assets	9,638	22,769
Property, plant and equipment, net	912	980
Operating lease right-of-use asset	762	903
Other assets	120	21
TOTAL ASSETS	\$ 11,432	\$ 24,673
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 1,707	\$ 2,245
Accrued compensation	1,021	2,161
Current portion of operating lease liability	211	196
Current portion of finance lease liability	8	28
Other current liabilities	45	58
Total current liabilities	2,992	4,688
Common stock warrant liability	—	6,868
Operating lease liability	601	760
Total liabilities	3,593	12,316
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of September 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of both September 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Series I convertible preferred stock as of September 30, 2023 and December 31, 2022, par value \$0.0001; authorized 1,049,280, issued and outstanding none and 1,049,280, respectively	—	—
Preferred stock as of both September 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of September 30, 2023 and December 31, 2022, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 1,864,265 and 536,394 shares, respectively	—	—
Additional paid-in capital	289,980	279,736
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(24)	(18)
Unrealized gain on marketable securities	—	56
Accumulated deficit	(282,117)	(267,417)
Total stockholders' equity	7,839	12,357
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 11,432	\$ 24,673

See notes to the condensed consolidated financial statements.



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

	Three months ended September 30		Nine months ended September 30	
	2023	2022	2023	2022
Net sales	\$ 2,412	\$ 2,065	\$ 6,313	\$ 6,204
Cost of goods sold	1,031	806	2,718	2,780
Gross profit	<u>1,381</u>	<u>1,259</u>	<u>3,595</u>	<u>3,424</u>
Operating expenses:				
Selling, general and administrative	3,428	4,251	13,582	12,920
Research and development	1,117	928	4,050	3,141
Total operating expenses	<u>4,545</u>	<u>5,179</u>	<u>17,632</u>	<u>16,061</u>
Loss from operations	(3,164)	(3,920)	(14,037)	(12,637)
Other income (expense), net	(204)	52	98	14
Change in fair value of warrant liability	—	—	(755)	—
Loss before income taxes	(3,368)	(3,868)	(14,694)	(12,623)
Income tax expense	<u>(2)</u>	<u>(2)</u>	<u>(6)</u>	<u>(6)</u>
Net loss	<u>\$(3,370)</u>	<u>\$(3,870)</u>	<u>\$(14,700)</u>	<u>\$(12,629)</u>
Basic and diluted loss per share	<u>\$ (1.81)</u>	<u>\$ (36.72)</u>	<u>\$ (10.21)</u>	<u>\$ (119.85)</u>
Weighted average shares outstanding – basic and diluted	1,864	105	1,439	105
Other comprehensive loss:				
Foreign currency translation adjustments	<u>\$ —</u>	<u>\$ 2</u>	<u>\$ (6)</u>	<u>\$ 1</u>
Total comprehensive loss	<u>\$(3,370)</u>	<u>\$(3,868)</u>	<u>\$(14,706)</u>	<u>\$(12,628)</u>

See notes to the condensed consolidated financial statements.

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

	Nine months ended September 30	
	2023	2022
Operating Activities:		
Net loss	\$(14,700)	\$(12,629)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	253	301
Stock-based compensation expense, net	513	697
Change in fair value of warrant liability	755	—
Net realized gain on marketable securities	(65)	—
Changes in operating assets and liabilities:		
Accounts receivable	(19)	(350)
Inventory, net	325	(113)
Other current assets	(551)	(40)
Other assets and liabilities	(16)	(142)
Accounts payable and accrued expenses	(1,678)	254
Net cash used in operating activities	(15,183)	(12,022)
Investing Activities:		
Proceeds from sale of marketable securities	578	—
Additions to intangible assets	(99)	—
Purchases of property and equipment	(185)	(103)
Net cash provided by (used in) investing activities	294	(103)
Financing Activities:		
Proceeds from ATM stock offerings, net	2,108	—
Payments on finance lease liability	(20)	(28)
Net cash provided by (used in) financing activities	2,088	(28)
Effect of exchange rate changes on cash	(6)	1
Net decrease in cash and cash equivalents	(12,807)	(12,152)
Cash and cash equivalents - beginning of period	<u>17,737</u>	<u>24,205</u>
Cash and cash equivalents - end of period	<u>\$ 4,930</u>	<u>\$ 12,053</u>
Supplemental cash flow information		
Inventory transferred to property, plant and equipment	\$ —	\$ 37
Non-cash impact of conversion of warrants to common stock (see Note 3)	\$ 6,868	\$ —

See notes to the condensed consolidated financial statements.

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

Note 1 — Nature of Business and Basis of Presentation

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

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

Principles of Consolidation: The accompanying condensed consolidated balance sheet as of December 31, 2022, which has been derived from the consolidated audited financial statements, and the unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Certain information and note disclosures normally included in the audited annual consolidated financial statements have been condensed or omitted pursuant to those rules and regulations. Accordingly, they do not include all of the information necessary for a fair presentation of results of operations, comprehensive loss, financial condition, and cash flows in conformity with U.S. GAAP. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented. Operating results for interim periods are not necessarily indicative of results that may be expected for the year as a whole. The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the consolidated financial statements and during the reporting period. Actual results could differ materially from these estimates.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022.

Going Concern: The Company’s consolidated financial statements have been prepared and presented on a basis assuming it continues as a going concern. During the years ended December 31, 2022 and 2021 and through September 30, 2023, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. As of September 30, 2023, the Company had an accumulated deficit of \$282.1 million and it expects to incur losses for the immediate future. To date, the Company has been funded by equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it will ever operate profitably. These factors raise substantial doubt about the Company’s ability to continue as a going concern through the next twelve months.

The Company became a revenue-generating company after acquiring the Aquadex Business in August 2016. The Company expects to incur additional losses in the near-term as it grows the Aquadex Business, including investments in its sales and marketing capabilities, product development, purchasing inventory, manufacturing components, generating additional clinical evidence supporting the efficacy of the Aquadex System, and complying with the requirements related to being a U.S. public company. To become and remain profitable, the Company must succeed in expanding the adoption and market acceptance of the Aquadex System. This will

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require the Company to succeed in training personnel at hospitals and in outpatient care settings, and effectively and efficiently manufacturing, marketing, and distributing the Aquadex System and related components. There can be no assurance that the Company will succeed in these activities, and it may never generate revenues sufficient to achieve profitability.

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

On March 3, 2023, we entered into a Sales Agreement with Ladenburg Thalmann & Co. Inc. ("Ladenburg") to create an at-the-market offering program under which we could offer and sell shares of our common stock having an aggregate offering price of up to \$10.0 million. Ladenburg was entitled to a commission at a fixed rate equal to 3% of the gross proceeds. For the three and nine months ending September 30, 2023, the Company issued shares under the at-the-market program for aggregate net proceeds of none and approximately \$2.1 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

The Company believes that its existing capital resources will be sufficient to support its operating plan through February 28, 2024. However, the Company will seek to raise additional capital to support its growth or other strategic initiatives through debt, equity or a combination thereof. There can be no assurance we will be successful in raising additional capital.

Revenue Recognition: The Company recognizes revenue in accordance with Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers, which the Company adopted effective January 1, 2018. Accordingly, the Company recognizes revenue when its customers obtain control of its products or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. See Note 2 – Revenue Recognition below for additional disclosures. For the three months ended September 30, 2023, two customers represented 21% and 11% of net sales. For the nine months ended September 30, 2023, two customers each represented 17% and 12% of net sales. For the three months ended September 30, 2022, one customer represented 12% of net sales. For the nine months ended September 30, 2022, two customers each represented 13% and 10% of net sales.

Accounts Receivable: Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of collectability, historical experience, and management's evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers' financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. To date, the Company has not experienced any write-offs or significant deterioration of the aging of its accounts receivable, and therefore, no allowance for doubtful accounts was considered necessary as of September 30, 2023, or December 31, 2022. As of September 30, 2023, three customers represented 17%, 17% and 11% of the accounts receivable balance. As of December 31, 2022, two customers represented 15% and 10% of the total accounts receivable balance.

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

<i>(in thousands)</i>	September 30, 2023	December 31, 2022
Finished Goods	\$ 811	\$ 993
Work in Process	170	204
Raw Materials	1,659	1,609
Inventory Reserves	<u>(304)</u>	<u>(145)</u>
Total	<u>\$2,336</u>	<u>\$2,661</u>

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

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

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

	September 30	
	2023	2022
Stock options	111,275	11,910
Warrants to purchase common stock	1,308,271	16,970
Series F convertible preferred stock	5,080	508
Total	<u>1,424,626</u>	<u>29,388</u>

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

	Three months ended September 30		Nine months ended September 30	
	2023	2022	2023	2022
<i>(in thousands, except per share amounts)</i>				
Net loss	<u>\$(3,370)</u>	<u>\$(3,870)</u>	<u>\$(14,700)</u>	<u>\$(12,629)</u>
Weighted average shares outstanding	<u>1,864</u>	<u>105</u>	<u>1,439</u>	<u>105</u>
Basic and diluted loss per share	<u>\$ (1.81)</u>	<u>\$(36.72)</u>	<u>\$ (10.21)</u>	<u>\$(119.85)</u>

Subsequent Events: The Company evaluates events through the date the consolidated financial statements are filed for events requiring adjustment to or disclosure in the consolidated financial statements. See note 10 – Subsequent Events for additional disclosures.

Note 2 — Revenue Recognition

Net Sales: The Company sells its products in the United States primarily through a direct salesforce. Customers who purchase the Company’s products include hospitals and clinics throughout the United States. In countries outside the United States, the Company sells its products through a limited number of specialty healthcare distributors in Austria, Brazil, Colombia, The Czech Republic, Germany, Greece, Hong Kong, India, Indonesia, Israel, Italy, Panama, Romania, Singapore, Slovakia, Spain, Switzerland, Thailand, United Arab Emirates, and the United Kingdom. These distributors resell the Company’s products to hospitals and clinics in their respective geographies. International revenue represents 5% of net sales for the three and nine months ended September 30, 2023 and 2022.

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

Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when the Company satisfies its performance obligations under the contract. The majority of the Company’s contracts have a single performance obligation and are short term in nature. The Company has entered into extended service plans with customers whose related revenue is recognized over time. This revenue represents less than 1% of net sales for the

three and nine months ended September 30, 2023 and 2022. The unfulfilled performance obligations related to these extended service plans are included in deferred revenue, which is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

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

Product Returns: The Company offers customers a limited right of return for its products in case of non-conformity or performance issues. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own historical sales and returns information. The Company has not received any returns to date and believes that future returns of its products will be minimal. Therefore, revenue recognized is not currently impacted by variable consideration related to product returns.

Note 3 — Stockholders' Equity

Series F Convertible Preferred Stock: On November 27, 2017, the Company closed on an underwritten public offering of Series F convertible preferred stock and warrants to purchase shares of common stock for gross proceeds of \$18.0 million. Net proceeds totaled approximately \$16.2 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The offering was comprised of Series F convertible preferred stock, convertible into shares of the Company's common stock at a conversion price of \$189,000 per share. Each share of Series F convertible preferred stock was accompanied by a Series 1 warrant, which expired on the first anniversary of its issuance, to purchase 16 shares of the Company's common stock at an exercise price of \$189,000 per share, and a Series 2 warrant, which expires on the seventh anniversary of its issuance, to purchase 4 shares of the Company's common stock at an exercise price of \$189,000 per share. The Series F convertible preferred stock has full ratchet price-based anti-dilution protection, subject to customary carve-outs, in the event of a down-round financing at a price per share below the conversion price of the Series F convertible preferred stock (which protection will expire if, during any 20 of 30 consecutive trading days, the volume weighted average price of the Company's common stock exceeds 300% of the then-effective conversion price of the Series F convertible preferred stock and the daily dollar trading volume for each trading day during such period exceeds \$200,000). The exercise price of the warrants is fixed and does not contain any variable pricing features, nor any price-based anti-dilutive features, apart from customary adjustments for stock splits, combinations, reclassifications, stock dividends or fundamental transactions. A total of 18,000 shares of Series F convertible preferred stock convertible into 96 shares of common stock and warrants to purchase 191 shares of common stock were issued in the offering.

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

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As of September 30, 2023, and December 31, 2022, 127 shares of the Series F convertible preferred stock remained outstanding.

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

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

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

October 2022 Offering: On October 18, 2022, the Company closed on an underwritten public offering of 209,940 shares of common stock and 23,157,124 shares of Series I convertible preferred stock, for gross proceeds of approximately \$11.0 million (the “October 2022 Offering”). Net proceeds totaled approximately \$9.4 million after deducting underwriting discounts and commissions and other costs associated with the offering and after giving effect to the underwriters’ full exercise of their over-allotment option.

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

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

On December 8, 2022, following a special meeting of stockholders, the Company’s board of directors approved a one-for-one hundred reverse stock split of the Company’s issued and outstanding shares of common stock (the “*Reverse Stock Split*”). On December 9, 2022, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on December 9, 2022, and the Company’s common stock began trading on a split-adjusted basis when the market opened on December 12, 2022. The conversion price of the preferred stock issued in the October 2022 offering was fixed and does not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock) or liquidation preference and, subject to limited exceptions, has no voting rights. The securities comprising the units are immediately separable and were issued separately. This reverse stock split did not change the par value of the Company’s common stock or the number of common or preferred shares authorized by the Company’s Fourth Amended and Restated Certificate of Incorporation, as amended. All share and per-share amounts in this quarterly report have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

On January 4, 2023, the Company secured stockholder approval for the exercisability of the common stock warrants issued in the October 2022 Offering. The warrants were subsequently determined to be equity-classified

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warrants and were marked to market, then reclassified to the equity section of the consolidated balance sheet. Through June 30, 2023, 660,046 common stock warrants had converted into 660,046 shares of common stock at a zero-dollar exercise price, with no proceeds received by the Company.

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

2023 At-the-Market Program: In March 2023, the Company filed a Prospectus Supplement to its Registration Statement on Form S-3 with the SEC in connection with a proposed At-the-Market Securities offering (the “At-the-Market Program”). During the three months and nine months ended September 30, 2023, the Company issued none and 657,333 shares of common stock under the At-the-Market Program for gross proceeds of none and approximately \$2.3 million, respectively. Net proceeds for the three and nine months ended September 30, 2023, totaled none approximately \$2.1 million, respectively, after deducting the underwriting discounts and commissions and other costs associated with the offering.

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

Market-Based Warrants: On May 30, 2019, the Company granted a market-based warrant to a consultant in exchange for investor relations services. The warrant represents the right to acquire up to 33 shares of the Company’s common stock at an exercise price of \$9,540 per share, based on the closing stock price of the Company’s common shares on May 30, 2019. The warrant is subject to a vesting schedule based on the Company achieving certain market stock prices within a specified period of time. The warrant expires on May 30, 2024 and had not vested as of September 30, 2023.

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

In conjunction with the Supply Agreement, the Company issued DaVita a warrant to purchase up to an aggregate of 1,289,081 shares of common stock of the Company, par value \$0.0001 per share, at an exercise price of \$3.2996 per share (the “**DaVita Warrant**”), provided that at no time can the DaVita Warrant be exercised for an amount of shares that would represent greater than 19.9% ownership in the Company subject to certain vesting milestones. The DaVita Warrant is expected to vest in four tranches as follows: (i) 25% upon receipt of notice to extend the Supply Agreement past the initial pilot-term; (ii) 25% upon the attainment by the Company of a net revenue achievement from DaVita’s efforts pursuant to the Supply Agreement within twelve months of Ultrafiltration Services Approval; (iii) 25% upon the attainment by the Company of a net revenue achievement from DaVita’s efforts pursuant to the Supply Agreement within twenty-four months of Ultrafiltration Services Approval; and (iv) 25% upon the attainment by the Company of a net revenue achievement from DaVita’s efforts pursuant to the Supply Agreement within thirty-six months of Ultrafiltration Services Approval. This warrant had not vested as of September 30, 2023.

The Company evaluated the accounting treatment for the DaVita Warrant pursuant to ASC 718, “Stock Compensation,” and ASC 480, “Distinguishing Liabilities from Equity,” and concluded that the DaVita Warrant should be classified as an equity instrument on the balance sheet as of September 30, 2023. In accordance with this treatment, the Company’s management concluded none of the performance-based vesting conditions of the DaVita warrant were probable of vesting as of September 30, 2023, and therefore, no expense associated with the DaVita Warrant was recognized in the Company’s financial statements as of that date. The Company will

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continue to evaluate the probability of achieving the performance milestones associated with the DaVita Supply Agreement and will record the related equity-based expense in its financial statements based on the grant date fair value of the DaVita Warrant when management deems it is probable that the performance-based vesting conditions will be achieved.

Note 4 — Stock-Based Compensation

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

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

<i>(in thousands)</i>	Three months ended September 30		Nine months ended September 30	
	2023	2022	2023	2022
Selling, general and administrative expense	\$133	\$199	\$484	\$624
Research and development expense	<u>2</u>	<u>21</u>	<u>29</u>	<u>73</u>
Total stock-based compensation expense	<u>\$135</u>	<u>\$220</u>	<u>\$513</u>	<u>\$697</u>

During the three months ended September 30, 2023 and 2022, under the 2017 Equity Incentive Plan, the 2021 Inducement Plan, and the 2013 Non-Employee Directors' Equity Incentive Plan, the Company granted 18,643 and 369 stock options, respectively, to its directors, officers and employees. During the nine months ended September 30, 2023 and 2022, the Company granted 125,410 and 5,577, respectively, to its directors, officers, employees and consultants. Vesting generally occurs over an immediate to 48-month period based on a time-of-service condition, although vesting acceleration is provided under one grant in the event that a certain milestone is met. The weighted-average grant date fair value of the stock-options issued during the three months ended September 30, 2023 and 2022 was \$1.63 and \$60.40 per share, respectively. The weighted-average grant date fair value of the stock options issued during the nine months ended September 30, 2023 and 2022 was \$6.18 and \$79.07 per share, respectively.

The total number of stock options outstanding as of September 30, 2023 and September 30, 2022 was 111,275 and 12,003, respectively.

The weighted-average assumptions used in the Black-Scholes option-pricing model are as follows for the stock options granted during the three and nine months ended September 30, 2023 and 2022:

	Three months ended September 30		Nine months ended September 30	
	2023	2022	2023	2022
Expected volatility	131.06%	132.08%	152.59%	132.48%
Expected Life of options (years)	6.25	6.25	6.19	6.15
Expected dividend yield	0%	0%	0%	0%
Risk-free interest rate	4.29%	3.02%	4.16%	2.13%

During the three months ended September 30, 2023 and 2022, 2,576 and 823 stock options vested, respectively, and 21,372 and 343 stock options were expired or forfeited during these periods, respectively. During the nine months ended September 30, 2023 and 2022, 5,022 and 2,730 stock options vested, respectively, and 24,620 and 1,148 stock options were expired or forfeited during these periods, respectively. During the three and nine months ended September 30, 2023 and 2022, no options were exercised.

Note 5 — Fair Value of Financial Instruments

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

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

- Level 1 — Financial instruments with unadjusted quoted prices listed on active market exchanges.

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

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

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

<i>(in thousands)</i>	September 30, 2023		December 31, 2022	
	Fair Value	Level 1	Fair Value	Level 1
Marketable securities	<u>\$0</u>	<u>\$0</u>	<u>\$569</u>	<u>\$569</u>

The fair value of the Company's common stock warrant liability related to the investor warrants issued in the October 2022 Offering was calculated using a Monte Carlo valuation model and was classified as Level 3 in the fair value hierarchy.

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

<i>(in thousands)</i>	
Balance at December 31, 2022	\$ 6,868
Change in fair value	755
Balance at January 4, 2023 (revaluation date)	7,623
Warrants reclassified to equity	<u>(7,623)</u>
Balance at September 30, 2023	<u>\$ —</u>

Note 6 — Income Taxes

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of its deferred tax assets. The Company has established a full valuation allowance for its U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying condensed consolidated financial statements.

As of September 30, 2023, there were no material changes to what the Company disclosed regarding tax uncertainties or penalties in its Annual Report on Form 10-K for the year ended December 31, 2022.

Note 7 — Operating Leases

The Company leases a 23,000 square foot facility located in Eden Prairie, Minnesota for office and manufacturing space under a non-cancelable operating lease that expires in March 2027. In November 2021, the Company entered into a fourth amendment to the lease, extending the term of the lease from March 31, 2022 to March 31, 2027. This facility serves as our corporate headquarters and houses substantially all our functional departments. Monthly rent and common area maintenance charges, including estimated property tax for our headquarters, total approximately \$32,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease. Beginning on April 1, 2022, the annual base rent was \$10.50 per square foot, subject to future annual increases of \$0.32 to \$0.34 per square foot.

Note 8 — Finance Lease Liability

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

Note 9 — Commitments and Contingencies

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

Milestone Payment: On December 27, 2022, the Company entered into a license and distribution agreement with SeaStar Medical Holding Corporation, (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of dysregulated immune responses including hyperinflammation on vital organs ("SeaStar"), appointing the Company as the exclusive U.S. distributor to promote, advertise, market, distribute and sell certain products. As a part of this agreement, the Company agreed to pay SeaStar, a milestone payment of \$450,000, upon its receipt of a Human Device Exemption (HDE) approval from the U.S. Food and Drug Administration's (FDA). This payment is due within 30 days after achievement of the milestone event. As of September 30, 2023, SeaStar had not obtained such HDE approval, but the Company believes approval is reasonably possible. No liability for this milestone payment has been recorded in the financial statements as of September 30, 2023.

Note 10 — Subsequent Events

Public Offering: On October 17, 2023, the Company closed on a public offering of 150,000 units (the "Units"), with each Unit consisting of one share of the Company's Series J Convertible Redeemable Preferred Stock, par value \$0.0001 per share, with a liquidation preference of \$25.00 per share (the "Series J Convertible Preferred Stock"), and one warrant (the "October 2023 Warrants") to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock.

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

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

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

The October 2023 Warrants have a term of three (3) years. Each October 2023 Warrant has an exercise price of \$7.50 (50.0% of the public offering price per Unit) per one-half of one share (0.5) of Series J Convertible Preferred Stock and is immediately exercisable.

The Company is currently evaluating the accounting treatment of the Series J Convertible Preferred Stock and the October 2023 Warrants.

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

**Up to 16,326,530 Units consisting of
16,326,530 Shares of Common Stock and
16,326,530 Common Warrants to purchase up to 16,326,530 Shares of Common Stock
Up to 16,326,530 Shares of Common Stock Underlying the Common Warrants included in the Units**

**Up to 16,326,530 Pre-Funded Units consisting of
16,326,530 Pre-Funded Warrants to purchase up to 16,326,530 Shares of Common Stock and
16,326,530 Common Warrants to purchase up to 16,326,530 Shares of Common Stock
Up to 16,326,530 Shares of Common Stock Underlying the Pre-Funded Warrants included in the Pre-
Funded Units
Up to 16,326,530 Shares of Common Stock Underlying the Common Warrants included in the Pre-Funded
Units**



PROSPECTUS

, 2024

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The estimated expenses payable by us in connection with the issuance and distribution of the securities being registered are as follows:

SEC Registration Fee	\$ 2,362
FINRA Filing Fee	\$ 1,250
Legal Fees and Expenses	\$250,000
Accounting Fees and Expenses	\$ 77,500
Miscellaneous Fees and Expenses	\$ 29,762
Transfer Agent and Registrar Fees	\$ 12,200
Total	\$373,074

Item 14. Indemnification of Directors and Officers.

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

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

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

- from any breach of the director's duty of loyalty to us or our stockholders;
- from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL; and
- from any transaction from which the director derived an improper personal benefit.
- We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacities as directors and officers.

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

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

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

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

Item 15. Recent Sales of Unregistered Securities.

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

- On June 19, 2023, the registrant granted a warrant to DaVita, Inc. ("DaVita"), pursuant to a Supply and Collaboration Agreement ("Supply Agreement") dated as of June 19, 2023, pursuant to which DaVita will pilot the Aquadex ultrafiltration therapy system to treat adult patients with congestive heart failure and related conditions within select U.S. markets. The warrant represents the right to purchase up to an aggregate of 1,289,081 shares of common stock of the Company, par value \$0.0001 per share, at an exercise price of \$3.2996 per share, provided that at no time can it be exercised for an amount of shares that would represent greater than 19.9% ownership in the Company (the "DaVita Warrant") subject to certain vesting milestones. The DaVita Warrant is expected to vest in four tranches as follows (i): 25% upon the Company's receipt of notice to extend the Supply Agreement past the initial pilot-term (the "Ultrafiltration Services Approval"); (ii) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within twelve months of the Ultrafiltration Services Approval; (iii) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within twenty-four months of Ultrafiltration Services Approval; and (iv) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within thirty-six months of Ultrafiltration Services Approval. This issuance was made in reliance upon the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

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Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

The following exhibits are filed as part of this registration statement:

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
1.1	Form of Placement Agency Agreement					X
1.2	Placement Agency Agreement dated as of October 12, 2023, by and between Nuwellis, Inc., Lake Street Capital Markets, LLC and Maxim Group LLC.	8-K	001-35312	October 17, 2023	1.1	
3.1	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1	
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1	
3.3	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	May 23, 2017	3.1	
3.4	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	October 12, 2017	3.1	
3.5	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1	
3.6	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K/A	001-35312	October 16, 2020	3.1	
3.7	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	April 27, 2021	3.1	
3.8	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	December 9, 2022	3.1	
3.9	Third Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2	
3.10	Amendment to Third Amended and Restated Bylaws	8-K	001-35312	October 5, 2022	3.1	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
3.11	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1	
3.12	Form of Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	S-1/A	333-221010	November 17, 2017	3.7	
3.13	Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State on October 16, 2023, with respect to the Series J Convertible Preferred Stock	8-K	001-35312	October 17, 2023	3.1	
4.1	Form of Warrant to Purchase Shares of Common Stock	S-1/A	333-221010	November 17, 2017	4.9	
4.2	Form of Series 1 and Series 2 Warrant to Purchase Shares of Common Stock	S-1/A	333-209102	February 25, 2019	4.10	
4.3	Common Stock Purchase Warrant, dated May 30, 2019, between the Company and Redington, Inc.	10-Q	001-35312	August 8, 2019	4.1	
4.4	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated October 23, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	October 23, 2019	4.1	
4.5	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.1	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
4.6	Form of Common Stock Pre-Funded Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.2	
4.7	Form of Common Stock Purchase Warrant	S-1/A	333-235385	January 23, 2020	4.15	
4.8	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated March 19, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 20, 2020	4.1	
4.9	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated March 30, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 30, 2020	4.1	
4.10	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated May 1, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	May 4, 2020	4.1	
4.11	Form of Warrant to Purchase Shares of Common Stock	S-1/A	333-24145	August 17, 2020	4.19	
4.12	Warrant to Purchase Shares of Common Stock	S-1/A	333-267368	October 13, 2022	4.20	
4.13	Form of Warrant to purchase shares of Series J Convertible Preferred Stock	S-1/A	333-274610	September 29, 2023	4.13	
4.14	Specimen of Common Stock Certificate	10	001-35312	September 30, 2011	4.1	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
4.15	DaVita Inc. Common Stock Warrant Agreement†	8-K	001-35312	June 21, 2023	4.1	
4.16	Form of Common Warrant					X
4.17	Form of Pre-Funded Warrant					X
4.18	Form of Warrant Agency Agreement					X
5.1	Opinion of Honigman LLP					X
10.1	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	10.1	
10.2	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A	
10.3	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	8-K	001-35312	May 29, 2013	10.2	
10.4	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2015	10.11	
10.5	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1	
10.6	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1	
10.7	Second Amendment to New-Hire Equity Incentive Plan†	S-8	333-202904	March 20, 2015	99.12	
10.8	Third Amendment to New-Hire Equity Incentive Plan†	S-8	333-210215	March 15, 2016	99.13	
10.9	Fourth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.4	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
<u>10.10</u>	Fifth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	January 18, 2018	10.1	
<u>10.11</u>	Sixth Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2019	10.2	
<u>10.12</u>	Seventh Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	December 6, 2019	10.1	
<u>10.13</u>	Eighth Amendment to New-Hire Equity Incentive Plan†	8-K/A	001-35312	February 25, 2021	10.1	
<u>10.14</u>	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.2	
<u>10.15</u>	2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.1	
<u>10.16</u>	First Amendment to the 2017 Equity Incentive Plan†	14A	001-35312	September 11, 2020	App. A	
<u>10.17</u>	Second Amendment to the 2017 Equity Incentive Plan†	10-K	001-35312	March 3, 2023	10.17	
<u>10.18</u>	Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.2	
<u>10.19</u>	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.3	
<u>10.20</u>	Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.1	
<u>10.21</u>	First Amendment to the 2021 Inducement Plan†	8-K	001-35312	April 21, 2022	10.1	
<u>10.22</u>	Second Amendment to the 2021 Inducement Plan†	8-K	001-35312	March 1, 2023	10.1	
<u>10.23</u>	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.2	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.24	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1	
10.25	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16	
10.26	Non-Employee Director Compensation Policy (effective August 18, 2021)†	10-Q	001-35312	November 10, 2021	10.2	
10.27	Non-Employee Director Compensation Policy (effective January 1, 2023) †	10-K	001-35312	March 3, 2023	10.27	
10.28	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18	
10.29	Second Amendment to Lease, dated as of April 20, 2015, by and between the Company and Capital Partners Industrial Fund I, LLLP dba Prairie Crossroads Business Center	8-K	001-35312	April 23, 2015	10.1	
10.30	Third Amendment to Lease, dated as of August 3, 2018, by and between the Company and Capital Partners Industrial Fund I, LLLP	10-Q	001-35312	November 7, 2018	10.2	
10.31	Fourth Amendment to Lease, dated as of November 18, 2021, by and between the Company and Capital Partners Industrial Fund I, LLLP	8-K	01-35312	November 23, 2021	10.1	
10.32	Warrant Agency Agreement between the Company and American Stock Transfer & Trust Company, LLC dated April 24, 2017	8-K	001-35312	April 25, 2017	10.1	
10.33	Form of Warrant Reprice Agreement	8-K	001-35312	June 29, 2018	10.1	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
<u>10.34</u>	Warrant Agency Agreement, dated as of March 12, 2019, between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-35312	March 13, 2019	4.2	
<u>10.35</u>	Underwriting Agreement, dated as of March 8, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	March 13, 2019	1.1	
<u>10.36</u>	Form of Employee Proprietary Information, Inventions Assignment and Non-Competition Agreement for the Company's employees, including executive officers†	10-Q	001-35312	May, 9, 2019	10.3	
<u>10.37</u>	Offer Letter, by and between the Company and Nestor Jaramillo, dated April 12, 2019†	10-Q	001-35312	May 9, 2019	10.5	
<u>10.38</u>	Placement Agency Agreement, dated as of October 23, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	October 23, 2019	1.1	
<u>10.39</u>	Form of Securities Purchase Agreement, dated as of October 23, 2019, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	October 23, 2019	10.1	
<u>10.40</u>	Placement Agency Agreement, dated as of November 4, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	November 4, 2019	1.1	
<u>10.41</u>	Form of Securities Purchase Agreement, dated as of November 4, 2019, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	November 4, 2019	10.1	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.42	Underwriting Agreement dated as of January 24, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	January 29, 2020	1.1	
10.43	Warrant Agency Agreement, dated as of January 28, 2020, between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-35312	January 29, 2020	4.2	
10.44	Placement Agency Agreement, dated as of March 19, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	March 20, 2020	1.1	
10.45	Form of Securities Purchase Agreement, dated as of March 19, 2020, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 20, 2020	10.1	
10.46	Placement Agency Agreement, dated as of March 30, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	March 30, 2020	1.1	
10.47	Form of Securities Purchase Agreement, dated as of March 30, 2020, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 30, 2020	10.1	
10.48	Form of Securities Purchase Agreement, dated as of May 1, 2020, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	May 4, 2020	10.1	
10.49	Underwriting Agreement, dated as of August 19, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	0001-35312	August 21, 2020	1.1	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.50	Warrant Agency Agreement, dated as of August 21, 2020, between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-35312	August 21, 2020	4.2	
10.51	Executive Employment Agreement, dated January 16, 2021, by and between the Company and Nestor Jaramillo, Jr.†	8-K	001-35312	January 19, 2021	10.1	
10.52	Executive Employment Agreement, dated January 16, 2021, by and between the Company and John L. Erb†	8-K	001-35312	January 19, 2021	10.2	
10.53	Offer Letter by and between the Company and George Montague, effective as of June 28, 2021†	8-K	001-35312	June 22, 2021	10.1	
10.54	Offer letter by and between the Company and Neil P. Ayotte, effective as of June 7, 2021†	10-Q	001-35312	August 12, 2021	10.4	
10.55	Offer Letter by and between the Company and Lynn Blake, effective as of October 19, 2022†	8-K	001-35312	October 5, 2022	10.1	
10.56	First Amendment to Offer Letter between the Company and Lynn Blake†	8-K	001-35312	December 9, 2022	10.1	
10.57	Underwriting Agreement dated September 15, 2021, between the Company and Ladenburg Thalmann & Co. Inc., as the Representative of the several underwriters named in Schedule I thereto	8-K	001-35312	September 17, 2021	1.1	
10.58	Warrant Agency Agreement, dated as of October 18, 2022, between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-35312	October 18, 2022	4.2	
10.59	Leak-Out Agreement	S-1/A	333-267368	September 30, 2022	10.70	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.60	Underwriting Agreement dated as of October 14, 2022, by and between Nuwellis, Inc. and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	October 18, 2022	1.1	
10.61	License and Distribution Agreement with SeaStar Medical Holding Corporation, dated as of December 27, 2022+	10-K	001-35312	March 3, 2023	10.63	
10.62	Supply and Collaboration Agreement dated as of June 19, 2023 by and between the Company and DaVita Inc. +	8-K	001-35312	June 21, 2023	10.1	
10.63	Registration Rights Agreement dated as of June 19, 2023 by and between the Company and DaVita Inc.	8-K	001-35312	June 21, 2023	10.2	
10.64	Transition Agreement, by and between Lynn Blake and the Company, dated as of August 4, 2023	8-K	001-35312	August 8, 2023	10.1	
10.65	Consulting Agreement, by and between Lynn Blake and the Company, dated as of August 4, 2023	8-K	001-35312	August 8, 2023	10.2	
10.66	Offer Letter, by and between Robert B. Scott and the Company, effective as of September 2, 2023	8-K	001-35312	August 18, 2023	10.1	
10.67	At The Market Offering Agreement, dated as of March 3, 2023, by and between the Company and Ladenburg Thalmann & Co. Inc.	10-K	001-35312	March 3, 2023	1.1	
10.68	Form of Warrant Agency Agreement	S-1/A	333-274610	September 29, 2023	10.68	
10.69	Form of Securities Purchase Agreement	S-1/A	333-274610	September 29, 2023	10.69	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.70	Form of Securities Purchase Agreement					X
21.1	List of Subsidiaries	10-K	001-35312	March 3, 2023	21	
23.1	Consent of Honigman LLP					(included in Exhibit 5.1)
23.2	Consent of Baker Tilly US					X
24.1	Power of Attorney	S-1	333-276562	January 18, 2024	24.1	
107	Filing Fee Table					X

† Indicates management compensatory plan, contract or arrangement.

+ Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request. Certain portions of the License and Distribution Agreement, Warrant, and the Supply and Collaboration Agreement have been redacted pursuant to Item 601(a)(6) and 601(b)(10)(iv) of Regulation S-K because the Company customarily and actually treats the redacted information as private or confidential and the omitted information is not material. Copies of the unredacted License and Distribution Agreement, Warrant, and Supply and Collaboration Agreement will be furnished to the SEC upon request.

(b) Financial Statement Schedules

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

Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Filing Fee Tables” or “Calculation of Registration Fee” table, as applicable, in the effective registration statement;
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; *provided, however,* that paragraphs (i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such

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post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser: each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (6) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- (7) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Eden Prairie, State of Minnesota, on this 30th day of January, 2024.

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr.

Nestor Jaramillo, Jr.

Chief Executive Officer

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>*</u> John L. Erb	Chairman of the Board	January 30, 2024
<u>*</u> Nestor Jaramillo, Jr.	President, Chief Executive Officer and Director (principal executive officer)	January 30, 2024
<u>*</u> Robert B. Scott	Chief Financial Officer (principal financial officer and principal accounting officer)	January 30, 2024
<u>*</u> Maria Rosa Costanzo, M.D.	Director	January 30, 2024
<u>*</u> Michael McCormick	Director	January 30, 2024
<u>*</u> Archelle Georgiou, M.D.	Director	January 30, 2024
<u>*</u> Gregory Waller	Director	January 30, 2024
<u>*</u> David McDonald	Director	January 30, 2024

By: /s/ Nestor Jaramillo, Jr.

Nestor Jaramillo, Jr.

Attorney-in-fact

PLACEMENT AGENCY AGREEMENT

[], 2024

Nuwellis, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344
Attention: Nestor Jaramillo, Jr., Chief Executive Officer
Dear Mr. Jaramillo:

This agreement (the “**Agreement**”) constitutes the agreement between Lake Street Capital Markets, LLC and Maxim Group LLC as placement agents (each, a “**Placement Agent**” and collectively, the “**Placement Agents**”) and Nuwellis, Inc., a Delaware corporation (together with its subsidiaries, the “**Company**”), pursuant to which the Placement Agents shall serve as the exclusive placement agents for the Company, on a “reasonable best efforts” basis, in connection with the proposed placement (the “**Placement**”) of (i) shares (the “**Shares**”) of common stock of the Company, par value \$0.0001 per share (the “**Common Stock**”), (ii) warrants (collectively, the “**Purchase Warrants**”) to purchase shares of Common Stock, and (iii) pre-funded warrants (collectively, the “**Pre-Funded Warrants**”) to purchase shares of Common Stock (the shares of Common Stock underlying the Purchase Warrants and the Pre-Funded Warrants, collectively with the Purchase Warrants, the Pre-Funded Warrants, and the Shares, the “**Securities**”). The terms of the Placement and the Securities shall be mutually agreed upon by the Company and the purchasers (each, a “**Purchaser**” and collectively, the “**Purchasers**”) and nothing herein constitutes that the Placement Agents would have the power or authority to bind the Company or any Purchaser or an obligation for the Company to issue any Securities or complete the Placement. The documents executed and delivered by the Company and the Purchasers in connection with the Placement, including, without limitation, a securities purchase agreement (the “**Purchase Agreement**”), shall be collectively referred to herein as the “**Transaction Documents**.” The purchase price to the Purchasers for each Common Unit is \$____, the purchase price to the Purchasers for each Pre-Funded Unit is \$____, the exercise price to the Purchaser for each share of Common Stock issuable upon exercise of the Pre-Funded Warrants is \$0.0001, and the exercise price to the Purchasers for each share of Common Stock issuable upon exercise of the Purchase Warrant is \$____. The Placement Agents may retain other brokers or dealers to act as sub-agents or selected-dealers on its behalf in connection with the Placement. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Purchase Agreement.

SECTION 1. REPRESENTATIONS AND WARRANTIES OF THE COMPANY; COVENANTS OF THE COMPANY.

A. Representations of the Company. Each of the representations and warranties (together with any related disclosure schedules thereto) and covenants made by the Company to the Purchasers in the Purchase Agreement in connection with the Placement is hereby incorporated herein by reference into this Agreement (as though fully restated herein) and is, as of the date of this Agreement and as of the Closing Date, hereby made to, and in favor of, the Placement Agents. In addition to the foregoing, the Company represents and warrants that:

1. Securities Law Filings. The Company has filed with the Securities and Exchange Commission (the “**Commission**”) a registration statement on Form S-1 (File No. 333-276562) under the Securities Act of 1933, as amended (the “**Securities Act**”), which was filed on January 18, 2024, as amended, and declared effective on [], 2024 for the registration of the Securities under the Securities Act. Following the determination of pricing among the Company and the prospective Purchasers introduced to the Company by Placement Agents, the Company will file with the Commission pursuant to Rules 430B, 430A and 424(b) under the Securities Act, and the rules and regulations (the “**Rules and Regulations**”) of the Commission promulgated thereunder, a final prospectus relating to the placement of the Securities, their respective pricings and the plan of distribution thereof and will advise the Placement Agents of all further information (financial and other) with respect to the Company required to be set forth therein. Such registration statement, at any given time, including the exhibits thereto filed at such time, as amended at such time, is hereinafter called the “**Registration Statement**”; such prospectus in the form in which it appears in the Registration Statement at the time of effectiveness is hereinafter called the “**Preliminary Prospectus**”; and the final prospectus, in the form in which it will be filed with the Commission pursuant to Rules 430A and/or 424(b) (including the Preliminary Prospectus as it may be amended or supplemented) is hereinafter called the “**Final Prospectus**.” The Registration Statement at the time it originally became effective is hereinafter called the “**Original Registration Statement**.” Any reference in this Agreement to the Registration Statement, the Original Registration Statement, the Preliminary Prospectus or the Final Prospectus shall be deemed to refer to and include the documents incorporated by reference therein (the “**Incorporated Documents**”), if any, which were or are filed under the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), at any given time, as the case may be; and any reference in this Agreement to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement, the Original Registration Statement, the Preliminary Prospectus or the Final Prospectus shall be deemed to refer to and include the filing of any document under the Exchange Act after the date of this Agreement, or the issue date of the Preliminary Prospectus or the Final Prospectus, as the case may be, deemed to be incorporated therein by reference. All references in this Agreement to financial statements and schedules and other information which is “contained,” “included,” “described,” “referenced,” “set forth” or “stated” in the Registration Statement, the Preliminary Prospectus or the Final Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Preliminary Prospectus or the Final Prospectus, as the case may be. As used in this paragraph and elsewhere in this Agreement, “**Time of Sale Disclosure Package**” means the Preliminary Prospectus, the Transaction Documents, the final terms of the Placement provided to the Purchasers (orally or in writing) and any issuer free writing prospectus as defined in Rule 433 of the Securities Act (each, an “**Issuer Free Writing Prospectus**”), if any, that the parties hereto shall hereafter expressly agree in writing to treat as part of the Time of Sale Disclosure Package. The term “any Prospectus” shall mean, as the context requires, the Preliminary Prospectus, the Final Prospectus, and any supplement to either thereof. The Company has not received any notice that the Commission has issued or intends to issue a stop order suspending the effectiveness of the Registration Statement or the use of the Preliminary Prospectus or the Final Prospectus or intends to commence a proceeding for any such purpose.

2. Assurances. The Original Registration Statement, as amended, (and any further documents to be filed with the Commission) contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the Securities Act and the applicable Rules and Regulations and did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Final Prospectus, as of its date, complied or will comply in all material respects with the Securities Act and the applicable Rules and Regulations. The Final Prospectus, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Incorporated Documents, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the applicable Rules and Regulations promulgated thereunder, and none of such documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (with respect to Incorporated Documents incorporated by reference in the Final Prospectus), in light of the circumstances under which they were made not misleading. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission. Except for this Agreement and the Transaction Documents, there are no documents required to be filed with the Commission in connection with the transaction contemplated hereby that (x) have not been filed as required pursuant to the Securities Act or (y) will not be filed within the requisite time period. Except for this Agreement and the Transaction Documents, there are no contracts or other documents required to be described in the Final Prospectus, or to be filed as exhibits or schedules to the Registration Statement, which have not been described or filed as required. The foregoing shall not apply to statements in, or omissions from, any such document made in reliance upon, and in conformity with, information furnished to the Company by the Placement Agents specifically for use in the preparation thereof.

3. Offering Materials. Neither the Company nor any of its directors and officers has distributed and none of them will distribute, prior to the Closing Date, any offering material in connection with the offering and sale of the Securities other than the Time of Sale Disclosure Package.

4. Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and the Time of Sale Disclosure Package and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of each of this Agreement and the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Company's Board of Directors (the "**Board of Directors**") or the Company's shareholders in connection therewith other than in connection with the Required Approvals (as defined in the Purchase Agreement). This Agreement has been duly executed by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

5. No Conflicts. The execution, delivery and performance by the Company of this Agreement, the Transaction Documents and the transactions contemplated pursuant to the Time of Sale Disclosure Package, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby to which it is a party do not and will not (i) conflict with or violate any provision of the Company's or any subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction upon any of the properties or assets of the Company, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a debt or otherwise) or other understanding to which the Company is a party or by which any property or asset of the Company is bound or affected, or (iii) subject to any required approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company is bound or affected; except in the case of each of clauses (ii) and (iii), such as would not reasonably be expected to result in a material adverse effect on: (x) the legality, validity or enforceability of any Transaction Document; (y) the results of operations, assets, business, or condition (financial or otherwise) of the Company; or (z) the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (x), (y), or (z), a "**Material Adverse Effect**").

6. Certificates. Any certificate signed by an officer of the Company and delivered to the Placement Agents or to Placement Agent Counsel (as defined below) shall be deemed to be a representation and warranty by the Company to the Placement Agents as to the matters set forth therein.

7. Reliance. The Company acknowledges that the Placement Agents will rely upon the accuracy and truthfulness of the foregoing representations and warranties and hereby consents to such reliance.

8. Forward-Looking Statements. No forward-looking statements (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Time of Sale Disclosure Package has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

9. Statistical or Market-Related Data. Any statistical, industry-related and market-related data included or incorporated by reference in the Time of Sale Disclosure Package, are based on or derived from sources that the Company reasonably and in good faith believes to be reliable and accurate, and such data agree with the sources from which they are derived.

10. Certain Fees; FINRA Affiliations. Except as set forth in the Registration Statement and Prospectus, no brokerage or finder's fees or commissions are or will be payable by the Company or any Affiliate (as defined in FINRA Rule 5121) of the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. There are no other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its shareholders that may affect the Placement Agents' compensation, as determined by FINRA. Other than payments to the Placement Agents for this Placement, the Company has not made and has no agreements, arrangements or understanding to make any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member participating in the offering as defined in FINRA Rule 5110 (a "**Participating Member**"); or (iii) any person or entity that has any direct or indirect affiliation or association with any Participating Member, within the 180-day period preceding the initial filing of the Registration Statement through the 60-day period after the effective date of the Registration Statement. None of the net proceeds of the Placement will be paid by the Company to any Participating Member or its affiliates, except as specifically authorized herein. Except as set forth in the Registration Statement and Prospectus, to the Company's knowledge, no officer, director or any beneficial owner of 10% or more of the Company's Common Stock or Common Stock Equivalents has any direct or indirect affiliation or association with any Participating Member in the Placement. Except for securities purchased on the open market and except as set forth in the Registration Statement and Prospectus, no Company Affiliate is an owner of stock or other securities of any Participating Member. No Company Affiliate has made a subordinated loan to any Participating Member. No proceeds from the sale of the Securities (excluding placement agent compensation as disclosed in the Registration Statement and the Prospectus) will be paid to any Participating Member, any persons associated with a Participating Member or an affiliate of a Participating Member. Except as disclosed in the Prospectus, the Company has not issued any warrants or other securities or granted any options, directly or indirectly, to the Placement Agents within the 180-day period prior to the initial filing date of the Prospectus. Except as set forth in the Registration Statement and Prospectus, no person to whom securities of the Company have been privately issued within the 180-day period prior to the initial filing date of the Prospectus is a Participating Member, is a person associated with a Participating Member or is an affiliate of a Participating Member. Except as set forth in the Registration Statement and Prospectus, no Participating Member in the Placement has a conflict of interest, as defined in FINRA Rule 5121, with the Company. "**FINRA member participating in the Placement**" includes any associated person of a Participating Member in the Placement, any member of such associated person's immediate family and any affiliate of a Participating Member in the Placement. When used in this Section 3.1(j) the term "affiliate of a FINRA member" or "affiliated with a FINRA member" means an entity that controls, is controlled by or is under common control with a FINRA member. The Company will advise the Representative and EGS if it learns that any officer, director or owner of 10% or more of the Company's outstanding Common Stock or Common Stock Equivalents is or becomes an affiliate or associated person of a Participating Member.

11. Board of Directors. The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the market or exchange on which the Common Stock is listed or quoted for trading (the "**Trading Market**"). In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent" as defined under the rules of the Trading Market.

12. D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires most recently completed by each of the Company's directors and officers is true and correct in all respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires become inaccurate and incorrect.

B. Covenants of the Company. The Company further covenants and agrees with the Placement Agents as follows:

1. Registration Statement Matters. The Company will advise the Placement Agents promptly after it receives notice thereof of the time when any amendment to the Registration Statement has been filed or becomes effective or any supplement to the Final Prospectus has been filed and will furnish the Placement Agents with copies thereof. The Company will file promptly all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Section 13(a), 14 or 15(d) of the Exchange Act subsequent to the date of any Prospectus and for so long as the delivery of a prospectus is required in connection with the Placement. The Company will advise the Placement Agents, promptly after it receives notice thereof (i) of any request by the Commission to amend the Registration Statement or to amend or supplement any Prospectus or for additional information, (ii) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or any order directed at any Incorporated Document, if any, or any amendment or supplement thereto or any order preventing or suspending the use of the Preliminary Prospectus or the Final Prospectus or any prospectus supplement or any amendment or supplement thereto or any post-effective amendment to the Registration Statement, of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, of the institution or threatened institution of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement or a Prospectus or for additional information, (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus; (v) of the receipt of any comments or request for any additional information from the Commission; and (vi) of the happening of any event during the period described in this Section 4(a) that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement or the Prospectus untrue or that requires the making of any changes in the Registration Statement or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Company shall use its best efforts to prevent the issuance of any such stop order or prevention or suspension of such use. If the Commission shall enter any such stop order or order or notice of prevention or suspension at any time, the Company will use its best efforts to obtain the lifting of such order at the earliest possible moment, or will file a new registration statement and use its best efforts to have such new registration statement declared effective as soon as practicable. Additionally, the Company agrees that it shall comply with the provisions of Rules 424(b), 430A, 430B and 430C, as applicable, under the Securities Act, including with respect to the timely filing of documents thereunder, and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) are received in a timely manner by the Commission.

2. Blue Sky Compliance. The Company will cooperate with the Placement Agents and the Purchasers in endeavoring to qualify the Securities for sale under the securities laws of such jurisdictions (United States and foreign) as the Placement Agents and the Purchasers may reasonably request and will make such applications, file such documents, and furnish such information as may be reasonably required for that purpose, provided the Company shall not be required to qualify as a foreign corporation or to file a general consent to service of process in any jurisdiction where it is not now so qualified or required to file such a consent, and provided further that the Company shall not be required to produce any new disclosure document. The Company will, from time to time, prepare and file such statements, reports and other documents as are or may be required to continue such qualifications in effect for so long a period as the Placement Agents may reasonably request for distribution of the Securities. The Company will advise the Placement Agents promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Securities for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof at the earliest possible moment.

3. Amendments and Supplements to a Prospectus and Other Matters. The Company will comply with the Securities Act and the Exchange Act, and the rules and regulations of the Commission thereunder, so as to permit the completion of the distribution of the Securities as contemplated in this Agreement, the Incorporated Documents and any Prospectus. If during the period in which a prospectus is required by law to be delivered in connection with the distribution of Securities contemplated by the Incorporated Documents or any Prospectus (the “**Prospectus Delivery Period**”), any event shall occur as a result of which, in the judgment of the Company or in the opinion of the Placement Agents or Placement Agent Counsel, it becomes necessary to amend or supplement the Incorporated Documents or any Prospectus in order to make the statements therein, in light of the circumstances under which they were made, as the case may be, not misleading, or if it is necessary at any time to amend or supplement the Incorporated Documents or any Prospectus or to file under the Exchange Act any Incorporated Document to comply with any law, the Company will promptly prepare and file with the Commission, and furnish at its own expense to the Placement Agents and to dealers, an appropriate amendment to the Registration Statement or supplement to the Registration Statement, the Incorporated Documents or any Prospectus that is necessary in order to make the statements in the Incorporated Documents and any Prospectus as so amended or supplemented, in light of the circumstances under which they were made, as the case may be, not misleading, or so that the Registration Statement, the Incorporated Documents or any Prospectus, as so amended or supplemented, will comply with law. Before amending the Registration Statement or supplementing the Incorporated Documents or any Prospectus in connection with the Placement, the Company will furnish the Placement Agents with a copy of such proposed amendment or supplement and will not file any such amendment or supplement to which the Placement Agents reasonably objects.

4. Copies of any Amendments and Supplements to a Prospectus. The Company will furnish the Placement Agents, without charge, during the period beginning on the date hereof and ending on the Closing Date of the Placement, as many copies of any Prospectus or prospectus supplement and any amendments and supplements thereto, as the Placement Agents may reasonably request.

5. Free Writing Prospectus. The Company covenants that it will not, unless it obtains the prior written consent of the Placement Agents, make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus required to be filed by the Company with the Commission or retained by the Company under Rule 433 of the Securities Act. In the event that the Placement Agents expressly consent in writing to any such free writing prospectus (a "**Permitted Free Writing Prospectus**"), the Company covenants that it shall (i) treat each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus, and (ii) comply with the requirements of Rule 164 and 433 of the Securities Act applicable to such Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping.

6. Transfer Agent and Warrant Agent. The Company will maintain, at its expense, a registrar and transfer agent for the shares of Common Stock and a warrant agent for the Purchase Warrants and Pre-Funded Warrants.

7. Earnings Statement. As soon as practicable and in accordance with applicable requirements under the Securities Act, but in any event not later than 18 months after the Closing Date, the Company will make generally available to its security holders and to the Placement Agents an earnings statement, covering a period of at least 12 consecutive months beginning after the Closing Date, that satisfies the provisions of Section 11(a) and Rule 158 under the Securities Act.

8. Periodic Reporting Obligations. During the Prospectus Delivery Period, the Company will duly file, on a timely basis, with the Commission and the Trading Market all reports and documents required to be filed under the Exchange Act within the time periods and in the manner required by the Exchange Act.

9. Additional Documents. The Company will enter into any subscription, purchase or other customary agreements as the Placement Agents or the Purchasers reasonably deem necessary or appropriate to consummate the Placement, all of which will be in form and substance reasonably acceptable to the Placement Agents and the Purchasers. The Company agrees that the Placement Agents may rely upon, and each is a third party beneficiary of, the representations and warranties, and applicable covenants, set forth in any such purchase, subscription or other agreement with Purchasers in the Placement.

10. No Manipulation of Price. Neither the Company, nor to its knowledge, any of its employees, directors or shareholders, has taken or will take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under the Exchange Act, or otherwise stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

11. Acknowledgment. The Company acknowledges that any advice given by the Placement Agents to the Company is solely for the benefit and use of the Board of Directors of the Company and may not be used, reproduced, disseminated, quoted or referred to, without the Placement Agents' prior written consent.

12. Publicity. The Company acknowledges and agrees that the Placement Agents may, subsequent to the Closing (as defined below), make public their involvement with the Placement. The Company agrees that, until 25 days after the final Closing Date, it will not issue press releases or engage in any other publicity, without the Placement Agents' prior written consent (not to be unreasonably withheld), other than normal and customary releases issued in the ordinary course of the Company's business. Notwithstanding the foregoing, in no event shall the Company be prohibited from issuing any press releases or engaging in any other publicity required by law, except that including the name of the Placement Agents therein shall require the prior written consent of the Placement Agents.

13. Reliance on Others. The Company confirms that it will rely on its own counsel and accountants for legal and accounting advice.

14. Research Matters. By entering into this Agreement, the Placement Agents do not provide any promise, either explicitly or implicitly, of favorable or continued research coverage of the Company and the Company hereby acknowledges and agrees that the Placement Agents' selection as placement agents for the Placement was in no way conditioned, explicitly or implicitly, on the Placement Agents providing favorable or any research coverage of the Company. In accordance with FINRA Rule 2241(b)(2), the parties acknowledge and agree that the Placement Agents have not directly or indirectly offered favorable research, a specific rating or a specific price target, or threatened to change research, a rating or a price target, to the Company or inducement for the receipt of business or compensation. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Placement Agents with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by the Placement Agents' investment banking divisions. The Company acknowledges that each of the Placement Agents is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short position in debt or equity securities of the Company.

15. Subsequent Equity Sales.

i. From the date hereof until ninety (90) days after the Closing Date, the Company shall not (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any Common Stock or Common Stock Equivalents or (ii) file any registration statement or amendment or supplement thereto, other than the Final Prospectus or filing a registration statement on Form S-8 in connection with any employee benefit plan, in each case without prior written consent of the Placement Agent.

ii. [Reserved].

iii. Notwithstanding the foregoing, this subsection shall not apply in respect of an Exempt Issuance. An "**Exempt Issuance**" means the issuance of (a) Common Stock or equity awards to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with automatic price resets, stock splits, adjustments or combinations as set forth in such securities) or to extend the term of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the 90-day period following the Closing Date, and provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company, an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

iv. [Reserved].

16. Lock-Up Agreements. On the Closing Date, the Placement Agents shall have received the executed lock-up agreements, in the form attached hereto as Exhibit A, from each of the directors and officers of the Company. The Company shall not amend, modify, waive or terminate any provision of any of the Lock-Up Agreements except to extend the term of the lock-up period and shall enforce the provisions of each Lock-Up Agreement in accordance with its terms. If any party to a Lock-Up Agreement breaches any provision of a Lock-Up Agreement, the Company shall promptly use its best efforts to seek specific performance of the terms of such Lock-Up Agreement.

17. FINRA. The Company shall advise the Placement Agents (who shall make an appropriate filing with FINRA) if it is aware that any officer, director, 10% or greater shareholder of the Company or Person that received the Company's unregistered equity securities in the past 180 days is or becomes an affiliate or associated person of a FINRA member firm prior to the earlier of the termination of this Agreement or the 60-day period after the effective date of the Registration Statement.

18. Trading Market. The Company will use its reasonable best efforts to maintain the listing of its Common Stock on the Trading Market for a period of at least two (2) years after the Closing Date.

19. Engagement of Professionals. The Company will retain a nationally recognized, PCAOB registered firm of independent certified public accountants reasonably acceptable to the Placement Agents for a period of at least three years after the Closing Date.

SECTION 2. REPRESENTATIONS OF THE PLACEMENT AGENT. Each of the Placement Agents represents and warrants that it (i) is a member in good standing of FINRA, (ii) is registered as a broker/dealer under the Exchange Act, (iii) is licensed as a broker/dealer under the laws of the states applicable to the offers and sales of the Securities by such Placement Agent, (iv) is and will be a body corporate validly existing under the laws of its place of incorporation, and (v) has full power and authority to enter into and perform its obligations under this Agreement. The Placement Agents will immediately notify the Company in writing of any change in their status as such. The Placement Agents covenant that they will use their reasonable best efforts to conduct the Placement hereunder in compliance with the provisions of this Agreement and the requirements of applicable law.

SECTION 3. COMPENSATION. In consideration of the services to be provided for hereunder, the Company shall pay to the Placement Agents or their respective designees their pro rata portion (based on the Securities placed) of the following compensation with respect to the Securities which they are placing:

A. A cash fee (the "**Cash Fee**") equal to an aggregate of eight percent (8.0%) of the aggregate gross proceeds raised in the Placement. The Cash Fee shall be paid at the closing of the Placement (the "**Closing**").

B. The Company agrees to pay all costs, fees and expenses incurred by the Company in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including, without limitation: (i) all expenses incident to the issuance, delivery and qualification of the Securities (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Common Stock; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Securities; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Preliminary Prospectus, the Final Prospectus, and all amendments thereto, and this Agreement; (vi) all attorneys' fees and expenses incurred by the Placement Agents in connection with the Placement up to a maximum of \$100,000; (vii) if applicable, the filing fees incident to the review and approval by the FINRA of the Placement Agents' participation in the offering and distribution of the Securities; (viii) the fees and expenses associated with including the Shares and Warrant Shares on the Trading Market; (ix) all costs and expenses incident to the travel and accommodation of the Company's and the Placement Agents' employees on the "roadshow," if any; and (x) all other fees, costs and expenses referred to in Part II of the Registration Statement. The Company will reimburse the Placement Agents directly upon the Closing from the gross proceeds raised in the Placement.

C. The Placement Agents reserve the right to reduce any item of their compensation or adjust the terms thereof as specified herein in the event that a determination shall be made by FINRA to the effect that such Placement Agents' aggregate compensation is in excess of FINRA rules or that the terms thereof require adjustment.

SECTION 4. INDEMNIFICATION.

(a) The Company agrees to indemnify and hold harmless the Placement Agents, their affiliates and each person controlling the Placement Agents (within the meaning of Section 15 of the Securities Act), and the directors, officers, agents and employees of the Placement Agents, their affiliates and each such controlling person (the Placement Agent, and each such entity or person, an “**Indemnified Person**”) from and against any losses, claims, damages, judgments, assessments, costs and other liabilities (collectively, the “**Liabilities**”), and shall reimburse each Indemnified Person for all fees and expenses (including the reasonable fees and expenses of one counsel for all Indemnified Persons, except as otherwise expressly provided herein) (collectively, the “**Expenses**”) as they are incurred by an Indemnified Person in investigating, preparing, pursuing or defending any action, suit, inquiry, notice of violation, proceeding or investigation (collectively, an “**Action**”), whether or not any Indemnified Person is a party thereto, (i) caused by, or arising out of or in connection with, any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, any Incorporated Document, or any Prospectus or by any omission or alleged omission to state therein a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading (other than untrue statements or alleged untrue statements in, or omissions or alleged omissions from, information relating to an Indemnified Person furnished in writing by or on behalf of such Indemnified Person expressly for use in the Incorporated Documents) or (ii) otherwise arising out of or in connection with advice or services rendered or to be rendered by any Indemnified Person pursuant to this Agreement, the transactions contemplated thereby or any Indemnified Person’s actions or inactions in connection with any such advice, services or transactions; provided, however, that, in the case of clause (ii) only, the Company shall not be responsible for any Liabilities or Expenses of any Indemnified Person that are finally judicially determined to have resulted solely from such Indemnified Person’s (x) gross negligence or willful misconduct in connection with any of the advice, actions, inactions or services referred to above or (y) use of any offering materials or information concerning the Company in connection with the offer or sale of the Securities in the Placement which were not authorized for such use by the Company and which use constitutes gross negligence or willful misconduct. The Company also agrees to reimburse each Indemnified Person for all Expenses as they are incurred in connection with enforcing such Indemnified Person’s rights under this Agreement.

(b) Upon receipt by an Indemnified Person of actual notice of an Action against such Indemnified Person with respect to which indemnity may be sought under this Agreement, such Indemnified Person shall promptly notify the Company in writing; provided that failure by any Indemnified Person so to notify the Company shall not relieve the Company from any liability which the Company may have on account of this indemnity or otherwise to such Indemnified Person, except to the extent the Company shall have been prejudiced by such failure. The Company shall, if requested by the Placement Agents, assume the defense of any such Action including the employment of counsel reasonably satisfactory to the Placement Agents, which counsel may also be counsel to the Company. Any Indemnified Person shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Person unless: (i) the Company has failed promptly to assume the defense and employ counsel or (ii) the named parties to any such Action (including any impeded parties) include such Indemnified Person and the Company, and such Indemnified Person shall have been advised in the reasonable opinion of counsel that there is an actual conflict of interest that prevents the counsel selected by the Company from representing both the Company (or another client of such counsel) and any Indemnified Person; provided that the Company shall not in such event be responsible hereunder for the fees and expenses of more than one firm of separate counsel for all Indemnified Persons in connection with any Action or related Actions, in addition to any local counsel. The Company shall not be liable for any settlement of any Action effected without its written consent (which shall not be unreasonably withheld). In addition, the Company shall not, without the prior written consent of the Placement Agents (which shall not be unreasonably withheld), settle, compromise or consent to the entry of any judgment in or otherwise seek to terminate any pending or threatened Action in respect of which indemnification or contribution may be sought hereunder (whether or not such Indemnified Person is a party thereto) unless such settlement, compromise, consent or termination includes an unconditional release of each Indemnified Person from all Liabilities arising out of such Action for which indemnification or contribution may be sought hereunder. The indemnification required hereby shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as such expense, loss, damage or liability is incurred and is due and payable.

(c) In the event that the foregoing indemnity is unavailable to an Indemnified Person other than in accordance with this Agreement, the Company shall contribute to the Liabilities and Expenses paid or payable by such Indemnified Person in such proportion as is appropriate to reflect (i) the relative benefits to the Company, on the one hand, and to the Placement Agents and any other Indemnified Person, on the other hand, of the matters contemplated by this Agreement or (ii) if the allocation provided by the immediately preceding clause is not permitted by applicable law, not only such relative benefits but also the relative fault of the Company, on the one hand, and the Placement Agents and any other Indemnified Person, on the other hand, in connection with the matters as to which such Liabilities or Expenses relate, as well as any other relevant equitable considerations; provided that in no event shall the Company contribute less than the amount necessary to ensure that all Indemnified Persons, in the aggregate, are not liable for any Liabilities and Expenses in excess of the amount of fees actually received by the Placement Agents pursuant to this Agreement. For purposes of this paragraph, the relative benefits to the Company, on the one hand, and to the Placement Agents on the other hand, of the matters contemplated by this Agreement shall be deemed to be in the same proportion as (a) the total value paid or contemplated to be paid to or received or contemplated to be received by the Company in the transaction or transactions that are within the scope of this Agreement, whether or not any such transaction is consummated, bears to (b) the fees paid to the Placement Agents under this Agreement. Notwithstanding the above, no person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act, as amended, shall be entitled to contribution from a party who was not guilty of fraudulent misrepresentation.

(d) The Company also agrees that no Indemnified Person shall have any liability (whether direct or indirect, in contract or tort or otherwise) to the Company for or in connection with advice or services rendered or to be rendered by any Indemnified Person pursuant to this Agreement, the transactions contemplated thereby or any Indemnified Person's actions or inactions in connection with any such advice, services or transactions except for Liabilities (and related Expenses) of the Company that are finally judicially determined to have resulted solely from such Indemnified Person's gross negligence or willful misconduct in connection with any such advice, actions, inactions or services.

(e) The reimbursement, indemnity and contribution obligations of the Company set forth herein shall apply to any modification of this Agreement and shall remain in full force and effect regardless of any termination of, or the completion of any Indemnified Person's services under or in connection with, this Agreement.

SECTION 5. ENGAGEMENT TERM. The Placement Agents' engagement hereunder shall become effective on the date hereof and shall continue until the earlier of (i) the Closing Date and (ii) June 27, 2024 (the "**Termination Date**"). Notwithstanding anything to the contrary contained herein, (i) the provisions concerning confidentiality, indemnification and contribution contained herein, (ii) the Company's obligations contained in the indemnification provisions will survive any expiration or termination of this Agreement, (iii) the Company's obligation to pay fees actually earned and payable and to reimburse expenses actually incurred and reimbursable pursuant to Section 3 hereof and which are permitted to be reimbursed under the FINRA Rules, and (iv) the Placement Agents' right to receive fees pursuant to Section 15 hereof, will survive any expiration or termination of this Agreement. Nothing in this Agreement shall be construed to limit the ability of the Placement Agents or their Affiliates to pursue, investigate, analyze, invest in, or engage in investment banking, financial advisory or any other business relationship with Persons (as defined below) other than the Company. As used herein (i) "**Persons**" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind and (ii) "**Affiliate**" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person as such terms are used in and construed under Rule 405 under the Securities Act. All such fees and reimbursements due shall be paid to the Placement Agents on or before the Termination Date (in the event such fees and reimbursements are earned or owed as of the Termination Date) or upon the Closing or any applicable portion thereof (in the event such fees are due pursuant to the terms of Section 3 hereof).

SECTION 6. PLACEMENT AGENT INFORMATION. The Company agrees that any information or advice rendered by the Placement Agents in connection with this engagement is for the confidential use of the Company only in their evaluation of the Placement and, except as otherwise required by law, the Company will not disclose or otherwise refer to the advice or information in any manner without the Placement Agents' prior written consent.

SECTION 7. NO FIDUCIARY RELATIONSHIP. This Agreement does not create, and shall not be construed as creating rights enforceable by any person or entity not a party hereto, except those entitled hereto by virtue of Section 4 hereof. The Company acknowledges and agrees that the Placement Agents are not and shall not be construed as a fiduciary of the Company and shall have no duties or liabilities to the equity holders or the creditors of the Company or any other person by virtue of this Agreement or the retention of such Placement Agents hereunder, all of which are hereby expressly waived.

SECTION 8. CLOSING. The Closing shall occur at the offices of Sullivan & Worcester LLP, located at 1633 Broadway, New York, New York 10019 (“**Placement Agent Counsel**”) (or at such other place as shall be agreed upon by the Placement Agents and the Company, including remotely via electronic transmission). Subject to the terms and conditions hereof and of the Purchase Agreement, at the Closing, payment of the purchase price for the Securities sold on the Closing Date shall be made by Federal Funds wire transfer, against delivery of such Securities, and such Securities shall be registered in such name or names and shall be in such denominations, as the Placement Agents may request at least one business day before the Closing Date. Deliveries of the documents with respect to the purchase of the Securities, if any, shall be made at the offices of Placement Agent Counsel. All actions taken at the Closing shall be deemed to have occurred simultaneously. The obligations of the Placement Agents, and the closing of the sale of the Securities hereunder are subject to the accuracy, when made and on the Closing Date, of the representations and warranties on the part of the Company contained herein and in the Purchase Agreement, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions, except as otherwise disclosed to and acknowledged and waived by the Placement Agents to the Company:

A. No stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been initiated or threatened by the Commission, and any request for additional information on the part of the Commission (to be included in the Registration Statement, the Preliminary Prospectus, the Final Prospectus or otherwise) shall have been complied with to the reasonable satisfaction of the Placement Agents. Any filings required to be made by the Company in connection with the Placement shall have been timely filed with the Commission.

B. The Placement Agents shall not have discovered and disclosed to the Company on or prior to the Closing Date that the Registration Statement, the Pricing Prospectus, the Final Prospectus or any amendment thereto contains an untrue statement of a fact which, in the reasonable opinion of Placement Agent Counsel, is material or omits to state any fact which, in the reasonable opinion of such counsel, is material and is required to be stated therein or is necessary to make the statements therein not misleading.

C. All corporate proceedings and other legal matters incident to the authorization, form, execution, delivery and validity of each of this Agreement, the Securities, the Registration Statement, the Preliminary Prospectus, the Final Prospectus and all other legal matters relating to this Agreement and the transactions contemplated hereby shall be reasonably satisfactory in all material respects to Placement Agent Counsel, and the Company shall have furnished to such counsel all documents and information that they may reasonably request to enable them to pass upon such matters.

D. The Placement Agents shall have received from outside counsel to the Company such counsel’s written opinion (including negative assurance), addressed to the Placement Agents and dated as of the Closing Date, in form and substance reasonably satisfactory to the Placement Agents and the Placement Agent Counsel.

E. On the date of this Agreement and on the Closing Date, the Placement Agents shall have received a certificate of the chief financial officer of the Company addressed to the Placement Agents and in form and substance satisfactory in all respects to the Placement Agents and Placement Agent Counsel.

F. On the Closing Date, Placement Agents shall have received a certificate of the chief executive officer of the Company, dated, as applicable, as of the date of such Closing, to the effect that, as of the date of this Agreement and as of the applicable date;

(i) the representations and warranties of the Company contained herein and in the Purchase Agreement were and are accurate in all material respects, except for such changes as are contemplated by this Agreement and except as to representations and warranties that were expressly limited to a state of facts existing at a time prior to the applicable Closing Date, and that, as of the applicable date, the obligations to be performed by the Company hereunder on or prior thereto have been fully performed in all material respects;

(ii) no stop order suspending the effectiveness of the Registration Statement or the use of the Final Prospectus has been issued and no proceedings for that purpose have been instituted or are pending or, to the Company's knowledge, threatened under the Securities Act; no order having the effect of ceasing or suspending the distribution of the Securities or any other securities of the Company has been issued by any securities commission, securities regulatory authority or stock exchange in the United States and no proceedings for that purpose have been instituted or are pending or, to the knowledge of the Company, contemplated by any securities commission, securities regulatory authority or stock exchange in the United States;

(iii) when the Registration Statement became effective, at the time of sale, and at all times subsequent thereto up to the delivery of such certificate, the Registration Statement and the Incorporated Documents, if any, when such documents became effective or were filed with the Commission, and any Prospectus, contained all material information required to be included therein by the Securities Act and the Exchange Act and the applicable rules and regulations of the Commission thereunder, as the case may be, and in all material respects conformed to the requirements of the Securities Act and the Exchange Act and the applicable rules and regulations of the Commission thereunder, as the case may be, and the Registration Statement and the Incorporated Documents, if any, and any Prospectus, did not and do not include any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading (provided, however, that the preceding representations and warranties contained in this paragraph (iii) shall not apply to any statements or omissions made in reliance upon and in conformity with information furnished in writing to the Company by the Placement Agents expressly for use therein) and, since the effective date of the Registration Statement, there has occurred no event required by the Securities Act and the rules and regulations of the Commission thereunder to be set forth in the Incorporated Documents which has not been so set forth; and

(iv) subsequent to the respective dates as of which information is given in the Registration Statement, the Incorporated Documents, if any, and the Final Prospectus, there has not been: (a) any Material Adverse Change (as defined below); (b) any transaction that is material to the Company taken as a whole, except transactions entered into in the ordinary course of business; (c) any obligation, direct or contingent, that is material to the Company taken as a whole, incurred by the Company, except obligations incurred in the ordinary course of business; (d) any material change in the capital stock (except changes thereto resulting from the exercise of outstanding stock options or warrants) or outstanding indebtedness of the Company; (e) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company; or (f) any loss or damage (whether or not insured) to the property of the Company which has been sustained or will have been sustained which has a Material Adverse Effect.

G. On the Closing Date, Placement Agents shall have received a certificate of the secretary of the Company, dated, as applicable, as of the date of such Closing, certifying to the organizational documents, good standing in the state of incorporation of the Company and board resolutions relating to the Placement of the Securities from the Company.

H. Neither the Company nor any of its subsidiaries (i) shall have sustained since the date of the latest audited financial statements included or incorporated by reference in the Registration Statement, the Preliminary Prospectus, the Final Prospectus, any loss or interference with its business from fire, explosion, flood, terrorist act or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth in or contemplated by the Registration Statement, the Preliminary Prospectus, the Final Prospectus, (ii) since such date there shall not have been any change in the capital stock or long-term debt of the Company or any of its subsidiaries or any change, or any development involving a prospective change, in or affecting the business, general affairs, management, financial position, stockholders' equity, results of operations or prospects of the Company and its Subsidiaries, otherwise than as set forth in or contemplated by the Registration Statement, the Preliminary Prospectus, the Final Prospectus, and (iii) since such date there shall not have been any new or renewed inquiries by the Commission, FINRA or any other regulatory body regarding the Company, the effect of which, in any such case described in clause (i), (ii) or (iii), is, in the judgment of the Placement Agents, so material and adverse as to make it impracticable or inadvisable to proceed with the sale or delivery of the Securities on the terms and in the manner contemplated by the Preliminary Prospectus, Time of Sale Disclosure Package and Final Prospectus.

I. The Common Stock is registered under the Exchange Act and, as of the Closing Date, the Shares and the shares of Common Stock underlying the Purchase Warrants and the Pre-Funded Warrants shall be listed and admitted and authorized for trading on the Trading Market or other applicable U.S. national exchange, or an application for such listing shall have been submitted to the Trading Market, and satisfactory evidence of such action shall have been provided to the Placement Agents. The Company shall have taken no action designed to, or likely to have the effect of terminating the registration of the Common Stock under the Exchange Act or delisting or suspending from trading the Common Stock from the Trading Market or other applicable U.S. national exchange, nor, except as disclosed in the Preliminary Prospectus, Time of Sale Disclosure Package and Final Prospectus, has the Company received any information suggesting that the Commission or the Trading Market or other U.S. applicable national exchange is contemplating terminating such registration or listing.

J. No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any governmental agency or body which would, as of the Closing Date, prevent the issuance or sale of the Securities or materially and adversely affect or potentially and adversely affect the business or operations of the Company; and no injunction, restraining order or order of any other nature by any federal or state court of competent jurisdiction shall have been issued as of the Closing Date which would prevent the issuance or sale of the Securities or materially and adversely affect or potentially and adversely affect the business or operations of the Company.

K. The Company shall have prepared and intend to file with the Commission a Current Report on Form 8-K with respect to the Placement prior to the deadline for filing such Current Report on Form 8-K.

L. FINRA shall have raised no objection to the fairness and reasonableness of the terms and arrangements of this Agreement. In addition, the Company shall, if requested by the Placement Agent, make or authorize Placement Agent Counsel to make on the Company's behalf, any filing with the FINRA Corporate Financing Department pursuant to FINRA Rule 5110 with respect to the Placement and pay all filing fees required in connection therewith.

M. On the date hereof, the Placement Agents shall have received, and the Company shall have caused to be delivered to the Placement Agents, a letter from the independent registered public accounting firm of the Company, addressed to the Placement Agents, dated as of the date hereof, in form and substance satisfactory to the Placement Agents. The letter shall not disclose any change in the condition (financial or other), earnings, operations, business or prospects of the Company from that set forth in the Registration Statement and the Preliminary Prospectus, which, in the Placement Agents' sole judgment, is material and adverse and that makes it, in the Placement Agents' sole judgment, impracticable or inadvisable to proceed with the Placement of the Securities as contemplated by such Registration Statement and Preliminary Prospectus. On the Closing Date, the Placement Agents shall have received from the independent registered public accounting firm of the Company, a letter dated as of the Closing Date, in form and substance satisfactory to the Placement Agents, to the effect that they reaffirm the statements made in the letter furnished pursuant to this subsection, except that the specified date referred to therein for the carrying out of procedures shall be no more than two business days prior to such Closing Date.

N. On the date hereof, the Placement Agents shall have received the executed lock-up agreement from each of the Company's directors and officers.

O. On the Closing Date, the Company shall provide the duly executed warrant agency agreement executed by and between the Company and the warrant agent.

P. Prior to the Closing Date, the Company shall have furnished to the Placement Agents such further information, certificates and documents as the Placement Agents may reasonably request.

Q. On the Closing Date, the Company shall deliver or shall cause to be delivered the Purchase Warrants and Pre-Funded Warrants registered in such name or names and in such denominations as the Placement Agents may request at least one business day before the Closing Date.

R. Subsequent to the execution and delivery of this Agreement and prior to the Closing Date, in the Placement Agents' sole judgment after consultation with the Company, there shall not have occurred any Material Adverse Effect or any material adverse change or development involving a prospective material adverse change in the condition or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement and Prospectus ("**Material Adverse Change**").

If any of the conditions specified in this Section 8 shall not have been fulfilled when and as required by this Agreement, or if any of the certificates, opinions, written statements or letters furnished to the Placement Agents or to Placement Agent Counsel pursuant to this Section 8 shall not be reasonably satisfactory in form and substance to the Placement Agents and to Placement Agent Counsel, all obligations of the Placement Agents hereunder may be cancelled by the Placement Agents at, or at any time prior to, the consummation of the Closing. Notice of such cancellation shall be given to the Company in writing or orally. Any such oral notice shall be confirmed promptly thereafter in writing.

SECTION 9. RIGHT OF FIRST REFUSAL. The parties hereto acknowledge that there is an ongoing right of first refusal in favor of the Placement Agents, as set forth in that certain placement agency agreement by and between the Company and the Placement Agents, dated October 12, 2023, which shall remain in place until April 17, 2024, and that nothing in this Agreement is intended to, nor shall be deemed to supersede, amend or obviate such right of first refusal.

SECTION 10. GOVERNING LAW. This Agreement will be governed by, and construed in accordance with, the laws of the State of New York applicable to agreements made and to be performed entirely in such State, without regard to the conflicts of laws principles thereof. This Agreement may not be assigned by either party without the prior written consent of the other party. This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective successors and permitted assigns. Any right to trial by jury with respect to any dispute arising under this Agreement or any transaction or conduct in connection herewith is waived. Any dispute arising under this Agreement may be brought into the courts of the State of New York or into the federal court located in New York, New York and, by execution and delivery of this Agreement, the Company hereby accepts for itself and in respect of its property, generally and unconditionally, the jurisdiction of aforesaid courts. Each party hereto hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by delivering a copy thereof via overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. The Company agrees that a final judgment in any such action, proceeding or counterclaim brought in any such court shall be conclusive and binding upon the Company and may be enforced in any other courts to the jurisdiction of which the Company is or may be subject, by suit upon such judgment. If either party shall commence an action or proceeding to enforce any provisions of a Transaction Document, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding. This paragraph shall survive any termination of this Agreement, in whole or in part.

SECTION 11. ENTIRE AGREEMENT/MISC. This Agreement (including the attached Indemnification Provisions) embodies the entire agreement and understanding between the parties hereto, and supersedes all prior agreements and understandings, relating to the subject matter hereof. For the avoidance of doubt, the Engagement Agreement, dated December 27, 2023 ("**Engagement Agreement**"), by and between the Company and the Placement Agents, shall continue to be effective and the terms therein, including, without limitation, Sections 5 with respect to any future offerings, shall continue to survive and be enforceable by the Placement Agents in accordance with its terms. If any provision of this Agreement is determined to be invalid or unenforceable in any respect, such determination will not affect such provision in any other respect or any other provision of this Agreement, which will remain in full force and effect. This Agreement may not be amended or otherwise modified or waived except by an instrument in writing signed by the Placement Agents and the Company. The representations, warranties, agreements and covenants contained herein shall survive the Closing and delivery of the Securities. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or a .pdf format file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or .pdf signature page were an original thereof.

SECTION 12. CONFIDENTIALITY. The Placement Agents (i) will keep the Confidential Information (as such term is defined below) confidential and will not (except as required by applicable law or stock exchange requirement, regulation or legal process (“**Legal Requirement**”), without the Company’s prior written consent, disclose to any person any Confidential Information, and (ii) will not use any Confidential Information other than in connection with the Placement. The Placement Agents further agree, severally and not jointly, to disclose the Confidential Information only to their Representatives (as such term is defined below) who need to know the Confidential Information for the purpose of the Placement, and who are informed by the Placement Agents of the confidential nature of the Confidential Information. The term “**Confidential Information**” shall mean, all confidential, proprietary and non-public information (whether written, oral or electronic communications) furnished by the Company to a Placement Agents or their Representatives (as defined below) in connection with such Placement Agents’ evaluation of the Placement. The term “**Confidential Information**” will not, however, include information which (i) is or becomes publicly available other than as a result of a disclosure by any of the Placement Agents or their Representatives in violation of this Agreement, (ii) is or becomes available to any of the Placement Agents or any of their Representatives on a non-confidential basis from a third-party, (iii) is known to any of the Placement Agents or any of their Representatives prior to disclosure by the Company or any of their Representatives, or (iv) is or has been independently developed by any of the Placement Agents and/or the Representatives without use of any Confidential Information furnished to it by the Company. The term “**Representatives**” shall mean the directors, board committees, officers, employees, financial advisors, attorneys and accountants of each of the Placement Agents. This provision shall be in full force until the earlier of (a) the date that the Confidential Information ceases to be confidential and (b) two (2) years from the date hereof. Notwithstanding any of the foregoing, in the event that any of the Placement Agents or any of their respective Representatives are required by Legal Requirement to disclose any of the Confidential Information, such Placement Agents and their respective Representatives will furnish only that portion of the Confidential Information which such Placement Agents or their respective Representative, as applicable, is required to disclose by Legal Requirement as advised by counsel, and will use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded the Confidential Information so disclosed.

SECTION 13. NOTICES. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of (a) the date of transmission, if such notice or communication is sent to the email address specified on the signature pages attached hereto prior to 6:30 p.m. (New York City time) on a business day, (b) the next business day after the date of transmission, if such notice or communication is sent to the email address on the signature pages attached hereto on a day that is not a business day or later than 6:30 p.m. (New York City time) on any business day, (c) the third business day following the date of mailing, if sent by U.S. internationally recognized air courier service, or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages hereto.

SECTION 14. PRESS ANNOUNCEMENTS. The Company agrees that the Placement Agents shall, from and after any Closing, have the right to reference the Placement and the Placement Agents’ role in connection therewith in the Placement Agents’ marketing materials and on its website and to place advertisements in financial and other newspapers and journals, in each case at its own expense.

SECTION 15. FEE TAIL. The Placement Agents shall be entitled to the cash fees calculated in the manner described in Section 3 hereto with respect to any private or public offering or other financing or capital raising transaction of any kind consummated within six (6) months from the Closing Date with an investor whom the Placement Agents have, directly or indirectly, introduced to the Company during the term of this Agreement. Notwithstanding the foregoing, this Section 15 shall not apply to any sale of equity securities to DaVita, Inc., a Delaware corporation (or any of its affiliates), Fresenius Medical Care North America, Innovative Renal Care, LLC, Sanderling Renal Services, Inc. or OrbiMed Advisors, LLC.

SECTION 16. SUCCESSORS. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 4 hereof, and to their respective successors, and personal representative, and no other person will have any right or obligation hereunder.

[The remainder of this page has been intentionally left blank.]

Please confirm that the foregoing correctly sets forth our agreement by signing and returning to the Placement Agents the enclosed copy of this Agreement.

Very truly yours,

LAKE STREET CAPITAL MARKETS, LLC

By: _____

Name: Michael Townley
Title: Head of Investment Banking

Address for notice:

920 Second Avenue South, Suite 700
Minneapolis, Minnesota 55402
Attention: Michael Townley, Head of Investment
Banking
Email: mike.townley@lakestreetcm.com

MAXIM GROUP LLC

By: _____

Name: Clifford A. Teller
Title: Co-President

Address for notice:

300 Park Ave., 16th Floor
New York, NY 10022
Attention: Clifford A. Teller
Email: cteller@maximgrp.com

With a copy to:

Sullivan & Worcester LLP
1633 Broadway
New York, New York 10019
Attention: David Danovitch, Esq. and Aaron
Schleicher, Esq.
Email: ddanovitch@sullivanlaw.com
and aschleicher@sullivanlaw.com

[Signature Page to Placement Agency Agreement
Between Lake Street Capital Markets, LLC, Maxim Group LLC and Nuwellis, Inc.]

Accepted and Agreed to as of
the date first written above:

NUWELLIS, INC.

By: _____

Name: Nestor Jaramillo, Jr.
Title: Chief Executive Officer

Address for notice:
12988 Valley View Road
Eden Prairie, Minnesota 55344

With a copy to:

Honigman, LLP
650 Trade Centre Way, Suite 200
Kalamazoo, Michigan 49002
Attention: Phillip D. Torrence
Email: PTorrence@honigman.com

[Signature Page to Placement Agency Agreement
Between Lake Street Capital Markets, LLC, Maxim Group LLC and Nuwellis, Inc.]

Exhibit A

Form of Lock-Up Agreement

FORM OF COMMON STOCK PURCHASE WARRANT

NUWELLIS, INC.

Warrant Shares: _____

Initial Exercise Date: [], 2024

THIS COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received by the Company, _____ or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the “Initial Exercise Date”) and on or prior to 5:00 p.m. (New York City time) on [_____, 2029¹] (the “Termination Date”) but not thereafter, to subscribe for and purchase from Nuwellis, Inc., a Delaware corporation (the “Company”), up to _____ shares of Common Stock (as subject to adjustment hereunder, the “Warrant Shares”). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee (“DTC”) shall initially be the sole registered holder of this Warrant, subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply. This Warrant is being issued pursuant to the Securities Purchase Agreement (as defined herein) and/or Registration Statement (as defined herein) and Warrant Agency Agreement (the “Warrant Agent Agreement”), dated as of [], 2024, between the Company and Equiniti Trust Company, LLC, and any successor warrant agent under thereunder (collectively, the “Warrant Agent”).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1.

“**Affiliate**” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“**Business Day**” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

“**Commission**” means the United States Securities and Exchange Commission.

“**Common Stock**” means the common stock of the Company, par value \$0.0001 per share, and any other class or series of securities into which such securities may hereafter be reclassified as or converted or otherwise changed into shares of the Company’s common stock, \$0.0001 par value per share.

“**Common Stock Equivalents**” means any securities of the Company that would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“**Person**” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

¹ Insert the date that is the five-year anniversary of the Initial Exercise Date, provided that, if such date is not a Trading Day, insert the immediately following Trading Day.

“**Registration Statement**” means the registration statement on Form S-1 filed with the Commission (File No. 276562), which was filed with the Commission and became effective on [], 2024.

“**Securities Act**” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“**Securities Purchase Agreement**” means that certain securities purchase agreement, dated [], 2024, among the Company and the purchasers signatory thereto.

“**Trading Day**” means a day on which the Common Stock is traded on a Trading Market.

“**Trading Market**” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“**Transfer Agent**” means Equiniti Trust Company, LLC, the current transfer agent of the Company, and any successor transfer agent of the Company.

Section 2. Exercise.

a) Exercise of Warrant. Subject to the provisions of Section 2(e) hereof, exercise of the subscription rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and prior to 5:00 p.m. (New York City time) on the Termination Date by delivery to the Warrant Agent and the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. Neither the Company nor the Warrant Agent shall have any obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. No ink original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company or the Warrant Agent until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Warrant Agent for cancellation within three (3) Trading Days after the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Warrant Agent shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver to the Holder and Warrant Agent any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase for a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a Holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The exercise price per [] share of Common Stock under this Warrant shall be \$[], subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with DTC through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate or book-entry notation, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company and the Warrant Agent of the Notice of Exercise, provided that payment of the aggregate Exercise Price (other than in the instance of a cashless exercise) is received by the Company or the Warrant Agent (as the case may be) one (1) Trading Day prior to such second Trading Day after the delivery of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company or the Warrant Agent (as the case may be) and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company and Warrant Agent of the Notice of Exercise, provided that payment of the aggregate Exercise Price (other than in the instance of a cashless exercise) is received by the Company or the Warrant Agent (as the case may be) one (1) Trading Day prior to such second Trading Day after the delivery of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). For the purposes of Regulation SHO under the Exchange Act, upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver or cause the delivery to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10.00 per Trading Day (increasing to \$20.00 per Trading Day on the fifth Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or the Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant is not held in global form through DTC (or any successor depository) and if this Warrant shall have been exercised in part, the Company shall (or shall direct the Warrant Agent), at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of this Warrant to subscribe for shares of Common Stock with an aggregate exercise price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. Notwithstanding any provision to the contrary contained in this Warrant, the Company shall not be required to issue any fraction of a Warrant Share or scrip representing fractional Warrant Shares upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder, and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto; and the Company shall use its best efforts to pay, or procure payment of issue or stamp taxes levied in connection with the issuance of the Warrant or Warrant Shares to the Holder ("Relevant Taxes"). The Holder agrees to cooperate with the Company and provide all necessary and reasonable information and documentation to the Company in a timely manner (and in any event within 10 Business Days of request) to enable the Company to procure payment of any Relevant Taxes and facilitate the making of any necessary filings in respect of Relevant Taxes required to be made within applicable time limits. The Company shall not be liable for any Relevant Taxes or any penalty, fine, surcharge, interest, charge, cost or other similar imposition arising in respect of Relevant Taxes to the extent that such amount arises or is increased as a result of any failure by a Holder to timely provide the Company with any information or documentation reasonably requested pursuant to this Section 2(d)(vi). The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to DTC (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of this Warrant that are not in compliance with the Beneficial Ownership Limitation (other than to the extent that information on the number of outstanding shares of Common Stock of the Company is provided by the Company and relied upon by the Holder). In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of this Warrant that are not in compliance with the Beneficial Ownership Limitation. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Share Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a share dividend or otherwise makes a distribution or distributions on its Common Stock or any other security of the Company that may be converted into Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any share capital of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and, in the case of a subdivision, combination or re-classification, shall become effective immediately after the effective date of such subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time that this Warrant is outstanding, the Company grants, issues or sells any Common Stock Equivalents or rights to purchase shares, warrants, securities or other property pro rata to all of the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, shares or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) other than dividends or distributions subject to Section 3(a) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall, subject to the terms of this Section 3(c), be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) or 50% or more of the voting power of the common equity of the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; *provided, however*, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity, as of the date of consummation of such Fundamental Transaction, the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of (1) the 30 day volatility, (2) the 100 day volatility or (3) the 365 day volatility, each of clauses (1)-(3) as obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the highest VWAP during the period beginning on the Trading Day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to this Section 3(e) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within five Business Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to customary written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable conditions or delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(d) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

e) Calculations. All calculations under this Section 3 shall be made by the Company to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by e-mail a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by e-mail to the Holder at its last e-mail address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its Warrant Agent, together with a written assignment of this Warrant substantially in the form attached hereto properly completed and duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver (or cause the Warrant Agent to deliver) a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depository), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company or the Warrant Agent, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a) herein and [Section 2.1.5]⁴ of the Warrant Agency Agreement, as to any transfer which may be involved in such division or combination, the Company shall execute and deliver (or cause the Warrant Agent to deliver) a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Initial Exercise Date and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the “Warrant Register”), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary. Notwithstanding the foregoing, nothing herein shall prevent the Warrant Agent or any agent of the Warrant Agent from giving effect to any written certification, proxy or other authorization furnished by DTC or any other depository governing the exercise of the rights of a holder of a beneficial interest in any Warrant. The rights of beneficial owners in a Warrant held in global form shall be exercised by the Holder or a Participant (as defined in the Warrant Agency Agreement) through the depository’s system, except to the extent expressly set forth in the Warrant Agency Agreement.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a “cashless exercise” pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company and the Warrant Agent of an affidavit of loss reasonably satisfactory to the Company and the Warrant Agent evidencing the loss, theft, destruction or mutilation of this Warrant or any share certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it and the Warrant Agent, and upon surrender and cancellation of such Warrant or share certificate, if mutilated, the Company will make and deliver (or cause the Warrant Agent to make and deliver) a new Warrant or share certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or share certificate.

⁴ Section reference TBD

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares. The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment of the Exercise Price for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue). Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of the Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant. Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof.

f) Jurisdiction. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, stockholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives, personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

g) Restrictions. The Holder acknowledges that the Warrant Shares issuable upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

h) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

i) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail (other than to the Warrant Agent) or sent by a nationally recognized overnight courier service, addressed to:

Nuwellis, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344
Attention: Nestor Jaramillo, Jr.
Email: nestor.jaramillo@nuwellis.com

Equiniti Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
Attention: Client Services

or such other e-mail address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail (or e-mail attachment) at the e-mail address set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via e-mail (or e-mail attachment) at the e-mail address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

j) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

k) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

l) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

m) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

n) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

o) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

p) Warrant Agency Agreement. This Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling; provided, however, that all provisions with respect to the rights, duties, obligations, protections, immunities and liability of the Warrant Agent only shall be determined and interpreted solely by the provisions of the Warrant Agency Agreement.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

NUWELLIS, INC.

By: _____
Name: Nestor Jaramillo, Jr.
Title: Chief Executive Officer

Dated: [____], 2024

Countersigned:

EQUINITI TRUST COMPANY, LLC.
as Warrant Agent

By: _____
Name:
Title:

Dated: [____], 2024

[Signature Page to Nuwellis, Inc. Common Warrant]

NOTICE OF EXERCISE

TO: EQUINITI TRUST COMPANY, LLC

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only required if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

DTC number:

Account name:

Account number:

[SIGNATURE OF HOLDER]

Name of Investing Entity:

Signature of Authorized Signatory of Investing Entity:

Name of Authorized Signatory:

Title of Authorized Signatory:

Date:

[Notice of Exercise for Nuwellis, Inc. Common Warrant]



EXHIBIT A
ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to:

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number:

Email Address:

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

FORM OF PRE-FUNDED COMMON STOCK PURCHASE WARRANT

NUWELLIS, INC.

Warrant Shares: _____

Initial Exercise Date: [], 2024

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received by the Company, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") until this Warrant is exercised in full (the "Termination Date") but not thereafter, to subscribe for and purchase from Nuwellis, Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee ("DTC") shall initially be the sole registered holder of this Warrant, subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply. This Warrant is being issued pursuant to the Securities Purchase Agreement (as defined herein) and/or Registration Statement (as defined herein) and Warrant Agency Agreement (the "Warrant Agent Agreement"), dated as of [], 2024, between the Company and Equiniti Trust Company, LLC, and any successor warrant agent under thereunder (collectively, the "Warrant Agent").

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1.

"**Affiliate**" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"**Business Day**" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"**Commission**" means the United States Securities and Exchange Commission.

"**Common Stock**" means the common stock of the Company, par value \$0.0001 per share, and any other class or series of securities into which such securities may hereafter be reclassified as or converted or otherwise changed into shares of the Company's common stock, \$0.0001 par value per share.

"**Common Stock Equivalents**" means any securities of the Company that would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"**Person**" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"**Registration Statement**" means the Company's registration statement on Form S-1 filed with the Commission (File No. 333-276562) which was filed with the Commission and became effective on [], 2024.

"**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“**Securities Purchase Agreement**” means that certain securities purchase agreement, dated [], 2024, among the Company and the purchasers signatory thereto.

“**Trading Day**” means a day on which the Common Stock is traded on a Trading Market.

“**Trading Market**” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“**Transfer Agent**” means Equiniti Trust Company, LLC, the current transfer agent of the Company, and any successor transfer agent of the Company.

Section 2. Exercise.

a) Exercise of Warrant. Subject to the provisions of Section 2(e) hereof, exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and prior to 5:00 p.m. (New York City time) on the Termination Date by delivery to the Warrant Agent and the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. Neither the Company nor the Warrant Agent shall have any obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. No ink original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company or the Warrant Agent until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Warrant Agent for cancellation within three (3) Trading Days after the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Warrant Agent shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver to the Holder and Warrant Agent any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase for a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a Holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder’s right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The aggregate exercise price of this Warrant, except for a nominal exercise price of \$0.0001 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of \$0.0001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever. The remaining unpaid exercise price per share of Common Stock under this Warrant shall be \$0.001, subject to adjustment hereunder (the “Exercise Price”).

c) Cashless Exercise. This Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. (“Bloomberg”) as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

“Bid Price” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with DTC through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder, or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate or book-entry notation, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company and the Warrant Agent of the Notice of Exercise, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by the Company or the Warrant Agent (as the case may be) one (1) Trading Day prior to such second Trading Day after the delivery of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price (other than in the case of a cashless exercise) to the Company or the Warrant Agent (as the case may be) and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company and Warrant Agent of the Notice of Exercise, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by the Company or the Warrant Agent (as the case may be) one (1) Trading Day prior to such second Trading Day after the delivery of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). For the purposes of Regulation SHO under the Exchange Act, upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver or cause the delivery to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10.00 per Trading Day (increasing to \$20.00 per Trading Day on the fifth Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Purchase Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant is not held in global form through DTC (or any successor depository) and if this Warrant shall have been exercised in part, the Company shall, (or shall direct the Warrant Agent), at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, cause the Warrant Agent to deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of this Warrant to subscribe for of shares of Common Stock with an aggregate exercise price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. Notwithstanding any provision to the contrary contained in this Warrant, the Company shall not be required to issue any fraction of a Warrant Share or scrip representing fractional Warrant Shares upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto; and the Company shall use its best efforts to pay, or procure payment of issue or stamp taxes levied in connection with the issuance of the Warrant or Warrant Shares to the Holder ("Relevant Taxes"). The Holder agrees to cooperate with the Company and provide all necessary and reasonable information and documentation to the Company in a timely manner (and in any event within 10 Business Days of request) to enable the Company to procure payment of any Relevant Taxes and facilitate the making of any necessary filings in respect of Relevant Taxes required to be made within applicable time limits. The Company shall not be liable for any Relevant Taxes or any penalty, fine, surcharge, interest, charge, cost or other similar imposition arising in respect of Relevant Taxes to the extent that such amount arises or is increased as a result of any failure by a Holder to timely provide the Company with any information or documentation reasonably requested pursuant to this Section 2(d)(vi). The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to DTC (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of this Warrant that are not in compliance with the Beneficial Ownership Limitation. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder and shall have no liability for exercises of this Warrant that are not in compliance with the Beneficial Ownership Limitation (other than to the extent that information on the number of outstanding shares of Common Stock of the Company is provided by the Company and relied upon by the Holder). For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Share Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a share dividend or otherwise makes a distribution or distributions on its Common Stock or any other security of the Company that may be converted into Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any share capital of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and, in the case of a subdivision, combination or re-classification, shall become effective immediately after the effective date of such subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time that this Warrant is outstanding, the Company grants, issues or sells any Common Stock Equivalents or rights to purchase shares, warrants, securities or other property pro rata to all of the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, share or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) other than dividends or distributions subject to Section 3(a) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall, subject to the terms of this Section 3(c), be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation). To the extent that this Warrant has not been partially or completely exercised at the time of such Distribution, such portion of the Distribution shall be held in abeyance for the benefit of the Holder until the Holder has exercised this Warrant.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction other than one in which a Successor Entity (as defined below) that is a publicly traded corporation whose stock is quoted or listed on a Trading Market assumes this Warrant such that the Warrant shall be exercisable for the publicly traded common stock of such Successor Entity and only if such Fundamental Transaction is within the Company’s control, the Company or any Successor Entity (as defined below) shall, at the Holder’s option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction, purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, if the Fundamental Transaction is not within the Company’s control, including not approved by the Company’s Board of Directors, Holder shall not have the option to require the Company to purchase its Warrant. Any cash payment will be made by wire transfer of immediately available funds within five Business Days of the Holder’s election (or, if later, on the effective date of the Fundamental Transaction). “Black Scholes Value” means the value of this Warrant based on the Black and Scholes Option Pricing Model obtained from the “OV” function on Bloomberg, L.P. (“Bloomberg”) determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of (1) the 30 day volatility or (2) the 100 day volatility, each of clauses (1)-(2) as obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(d) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

e) Calculations. All calculations under this Section 3 shall be made by the Company to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by e-mail a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by e-mail to the Holder at its last e-mail address as it shall appear upon the Warrant Register of the Company, at least twenty calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its Warrant Agent, together with a written assignment of this Warrant substantially in the form attached hereto properly completed and duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver (or cause the Warrant Agent to deliver) a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depository), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company or the Warrant Agent, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a) herein and [Section 21.5]¹ of the Warrant Agency Agreement, as to any transfer which may be involved in such division or combination, the Company shall execute and deliver (or cause the Warrant Agent to deliver) a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Initial Exercise Date and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

¹ Section reference TBD.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the “Warrant Register”), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary. Notwithstanding the foregoing, nothing herein shall prevent the Warrant Agent or any agent of the Warrant Agent from giving effect to any written certification, proxy or other authorization furnished by DTC or any other depository governing the exercise of the rights of a holder of a beneficial interest in any Warrant. The rights of beneficial owners in a Warrant held in global form shall be exercised by the Holder or a Participant (as defined in the Warrant Agency Agreement) through the depository’s system, except to the extent expressly set forth in the Warrant Agency Agreement.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a “cashless exercise” pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company and the Warrant Agent of an affidavit of loss reasonably satisfactory to the Company and the Warrant Agent evidencing the loss, theft, destruction or mutilation of this Warrant or any share certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it and the Warrant Agent, and upon surrender and cancellation of such Warrant or share certificate, if mutilated, the Company will make and deliver (or cause the Warrant Agent to make and deliver) a new Warrant or share certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or share certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares. The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue). Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of the Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant. Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof.

f) Jurisdiction. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, stockholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives, waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

g) Restrictions. The Holder acknowledges that the Warrant Shares issuable upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

h) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

i) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail (other than to the Warrant Agent) or sent by a nationally recognized overnight courier service, addressed to:

Nuwellis, Inc.
12988 Valley View Road
Eden Prairie, Minnesota 55344
Attention: Nestor Jaramillo, Jr.
Email: nestor.jaramillo@nuwellis.com

Equiniti Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
Attention: [Client Services]

or such other e-mail address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail (or e-mail attachment) at the e-mail address set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via e-mail (or e-mail attachment) at the e-mail address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

j) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

k) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

l) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

m) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

n) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

o) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

p) Warrant Agency Agreement. This Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling; provided, however, that all provisions with respect to the rights, duties, obligations, protections, immunities and liability of the Warrant Agent only shall be determined and interpreted solely by the provisions of the Warrant Agency Agreement.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

NUWELLIS, INC.

By: _____
Name: Nestor Jaramillo, Jr.
Title: Chief Executive Officer

Dated: [____], 2024

Countersigned:

EQUINITI TRUST COMPANY, LLC,
as Warrant Agent

By: _____
Name:
Title:

Dated: [____], 2024

[Signature Page to Nuwellis, Inc. Pre-Funded Warrant]

NOTICE OF EXERCISE

TO: EQUINITI TRUST COMPANY, LLC

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only required if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

DTC number: _____
Account name: _____
Account number: _____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

[Signature Page to Nuwellis, Inc. Pre-Funded Warrant]



EXHIBIT A
ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____ (Please Print)

Address: _____ (Please Print)

Phone Number:

Email Address:

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

WARRANT AGENCY AGREEMENT

WARRANT AGENCY AGREEMENT (this "Warrant Agency Agreement") dated as of [], 2024 (the "Issuance Date") between Nuwellis, Inc., a company incorporated under the laws of the State of Delaware (the "Company"), and Equiniti Trust Company, LLC, a New York limited liability company ("Equiniti") (the "Warrant Agent").

WHEREAS, pursuant to the terms of that certain placement agency agreement (the "Placement Agency Agreement"), dated [], 2024, by and between the Company, Lake Street Capital Markets, LLC and Maxim Group LLC, the Company is engaged in a public offering (the "Offering") of (i) [] units (the "Units"), with each Unit consisting of (A) [] shares (the "Shares") of the Company's common stock, par value \$0.0001 per share (the "Common Stock"), and (B) [] warrants (the "Common Warrants") to purchase [] shares of Common Stock, (ii) for some purchasers, in lieu of Shares, [] pre-funded warrants to purchase [] shares of Common Stock (the "Pre-Funded Warrants") and together with the Common Warrants, the "Warrants"), and (iii) the shares of Common Stock issuable upon exercise of the Warrants (the "Warrant Shares").

WHEREAS, the Company has filed with the Securities and Exchange Commission (the "Commission") a Registration Statement on Form S-1 (File No. 333-276562) (as the same may be amended from time to time, the "Registration Statement"), for the registration under the Securities Act of 1933, as amended (the "Securities Act"), of the Units, the Common Stock, the Warrants, and the Warrant Shares, and such Registration Statement was declared effective on [], 2024;

WHEREAS, the Company desires the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing to so act, in accordance with the terms set forth in this Warrant Agency Agreement in connection with the issuance, registration, transfer, exchange and exercise of the Warrants;

WHEREAS, the Company desires to provide for the provisions of the Warrants, the terms upon which they shall be issued and exercised, and the respective rights, limitation of rights, and immunities of the Company, the Warrant Agent, and the holders of the Warrants, as applicable; and

WHEREAS, all acts and things have been done and performed which are necessary to make the Warrants the valid, binding and legal obligations of the Company, and to authorize the execution and delivery of this Warrant Agency Agreement.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, the parties hereto agree as follows:

1. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company with respect to the Warrants in accordance with the express terms and conditions hereof, and the Warrant Agent hereby accepts such appointment and agrees to perform the same in accordance with the express terms and conditions set forth in this Warrant Agency Agreement (and no implied terms or conditions).

2. Warrants. The Warrants shall be registered securities in book-entry form and shall initially be evidenced by a global certificate in the form of Exhibit A (the “Global Certificate”) attached to this Warrant Agency Agreement, which shall be deposited on behalf of the Company with a custodian for The Depository Trust Company (“DTC”) and registered in the name of Cede & Co., a nominee of DTC. If DTC subsequently ceases to make its book-entry settlement system available for the Warrants, the Company shall instruct the Warrant Agent regarding making other arrangements for book-entry settlement. In the event that the Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Company shall instruct the Warrant Agent to provide written instructions to DTC to deliver to the Warrant Agent for cancellation the Global Certificate or Certificates, and the Company shall instruct the Warrant Agent to deliver to DTC separate certificates evidencing Warrants (“Definitive Certificates” and, together with the Global Certificate, “Warrant Certificates”) registered as requested through the DTC system. The Definitive Certificates, together with the form of election to purchase shares of Common Stock (the “Notice of Exercise”) and the form of assignment to be printed on the reverse thereof, shall be substantially in the form of Exhibit B attached hereto.

2.1. Issuance and Registration of Warrants.

2.1.1. Warrant Register. The Warrant Agent shall maintain books (“Warrant Register”) for the registration of original issuance and the registration of transfer of the Warrants.

2.1.2. Issuance of Warrants. Upon the initial issuance of the Warrants, the Warrant Agent shall issue the Global Certificates and deliver the Warrants in the DTC book-entry settlement system in accordance with written instructions delivered to the Warrant Agent by the Company. Ownership of beneficial interests in the Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained (i) by DTC and (ii) by institutions that have accounts with DTC (each, a “Participant”). A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent and the Company for the exchange of some or all of such Holder’s Warrants held in book-entry form for a Definitive Certificate evidencing the same number of Warrants, which request shall be in the form attached hereto as Annex A (such notice, the “Warrant Certificate Request Notice” and the date of delivery of such Warrant Certificate Request Notice by the Holder, the “Warrant Certificate Request Notice Date” and the actual surrender upon delivery by the Holder of a number of Warrants in the DTC book-entry settlement system for the same number of Warrants evidenced by a Definitive Certificate, a “Warrant Exchange”), the Warrant Agent shall, as promptly as practicable, effect the Warrant Exchange and the Company shall promptly issue and deliver (or cause to be delivered) to the Holder a Definitive Certificate for such number of Warrants in the name set forth in the Warrant Certificate Request Notice. Such Definitive Certificate shall be dated the original issue date of the Warrants and shall be executed manually or by facsimile signature by an authorized signatory of the Company and shall be in the form attached hereto as Exhibit B. In connection with a Warrant Exchange, the Company agrees to deliver, or to direct the Warrant Agent to deliver, the Definitive Certificate to the Holder within three (3) Trading Days of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate Request Notice (“Warrant Certificate Delivery Date”). If the Company fails for any reason to deliver or cause the delivery to the Holder the Definitive Certificate subject to the Warrant Certificate Request Notice by the Warrant Certificate Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares evidenced by such Definitive Certificate, of the Common Stock on the Warrant Certificate Request Notice Date), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Certificate Delivery Date until such Definitive Certificate is delivered or, prior to delivery of such Warrant Certificate, the Holder rescinds such Warrant Exchange.

The Company covenants and agrees that, upon the date of delivery of the Warrant Certificate Request Notice, the Holder shall be deemed to be the holder of the Definitive Certificate and, notwithstanding anything to the contrary set forth herein, the Definitive Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Warrants evidenced by such Definitive Certificate and the terms of this Warrant Agency Agreement. A party requesting a Warrant Exchange must provide to the Warrant Agent any evidence of authority that may reasonably be required by the Warrant Agent, including but not limited to, a signature guarantee.

2.1.3. Beneficial Owner; Holder. Prior to due presentment for registration of transfer of any Warrant, the Company and the Warrant Agent shall deem and treat the person in whose name that Warrant shall be registered on the Warrant Register (the “Holder”) as the absolute owner of such Warrant for purposes of any exercise thereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Notwithstanding the foregoing, nothing herein shall prevent the Company, the Warrant Agent or any agent of the Company or the Warrant Agent from giving effect to any written certification, proxy or other authorization furnished by DTC governing the exercise of the rights of a holder of a beneficial interest in any Warrant. The rights of beneficial owners in a Warrant evidenced by the Global Certificate shall be exercised by the Holder or a Participant through the DTC system, except to the extent set forth herein or in the Global Certificate.

2.1.4. Execution. The Warrant Certificates shall be executed on behalf of the Company by any authorized officer of the Company (an “Authorized Officer”), which need not be the same authorized signatory for all of the Warrant Certificates, either manually or by facsimile signature. The Warrant Certificates shall be countersigned, either manually or by facsimile signature, by an authorized signatory of the Warrant Agent, which need not be the same signatory for all of the Warrant Certificates, and no Warrant Certificate shall be valid for any purpose unless so countersigned. In case any Authorized Officer of the Company that signed any of the Warrant Certificates ceases to be an Authorized Officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant Certificates, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Warrant Certificates had not ceased to be such officer of the Company; and any Warrant Certificate may be signed on behalf of the Company by any other person who, at the actual date of the execution of such Warrant Certificate, shall be an Authorized Officer of the Company authorized to sign such Warrant Certificate, although at the date of the execution of this Warrant Agency Agreement any such person was not such an Authorized Officer.

2.1.5. Registration of Transfer. Subject to the provisions of the Warrants, at any time prior to 5:00 p.m. (New York City time) on the Termination Date (as defined below), a transfer of any Warrants may be registered and any Warrant Certificate or Warrant Certificates may be split up, combined or exchanged for another Warrant Certificate or Warrant Certificates evidencing the same number of Warrants as the Warrant Certificate or Warrant Certificates surrendered. Any Holder desiring to register the transfer of Warrants or to split up, combine or exchange any Warrant Certificate shall make such request in writing delivered to the Warrant Agent, and shall surrender to the Warrant Agent the Warrant Certificate or Warrant Certificates evidencing the Warrants the transfer of which is to be registered or that is or are to be split up, combined or exchanged together with any required form of assignment and certificate duly executed and properly completed by such Holder at the office or offices of the Warrant Agent designated for such purpose and, in the case of registration of transfer, shall provide a signature guarantee (a “signature guarantee”) from an eligible guarantor institution participating in a signature guarantee program approved by the Securities Transfer Association and such other documentation as the Warrant Agent may reasonably request. Thereupon, the Warrant Agent shall countersign and deliver to the person entitled thereto a Warrant Certificate or Warrant Certificates, as the case may be, as so requested. The Company and the Warrant Agent may require payment, by the Holder requesting a registration of transfer of Warrants or a split-up, combination or exchange of a Warrant Certificate (but, for purposes of clarity, not upon the exercise of the Warrants and issuance of Warrant Shares to the Holder), of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with such registration of transfer, split-up, combination or exchange, together with reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto. The Warrant Agent shall not have any duty or obligation to take any action under any section of this Warrant Agreement that requires the payment of taxes and/or charges unless and until it is satisfied that all such payments have been made.

2.1.6. Loss, Theft and Mutilation of Warrant Certificates. Upon receipt by the Company and the Warrant Agent of evidence reasonably satisfactory to them of the loss, theft, destruction or mutilation of a Warrant Certificate, which evidence shall include an affidavit of loss, or in the case of mutilated certificates, the certificate or portion thereof remaining, and, in case of loss, theft or destruction, of indemnity or security in customary form and amount satisfactory to the Warrant Agent, and satisfaction of any other reasonable requirements, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Company shall make and deliver a new Warrant Certificate of like tenor to the Warrant Agent for countersignature and delivery to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated. The Warrant Agent may charge the Holder an administrative fee for processing the replacement of lost Warrant Certificates, which shall be charged only once in instances where a single surety bond obtained covers multiple certificates. The Warrant Agent may receive compensation from the surety companies or surety agents for administrative services provided to them.

2.1.7. Proxies. The Holder of a Warrant may grant proxies or otherwise authorize any person, including the Participants and beneficial holders that may own interests through the Participants, to take any action that a Holder is entitled to take under this Warrant Agency Agreement or the Warrants; provided, however, that at all times that Warrants are evidenced by a Global Certificate, exercise of those Warrants shall be effected on their behalf by Participants through DTC in accordance the procedures administered by DTC.

2.1.8. Opinion of Counsel. On or prior to the execution of this Warrant Agency Agreement, the Company shall provide the Warrant Agent with an opinion of counsel to set up a reserve of Warrant Shares for the outstanding Warrants. The opinion shall state that all Warrants or Warrant Shares, as applicable, are (a) registered under the Securities Act of 1933, as amended (the "Securities Act"), or are exempt from such registration, and all appropriate state securities law filings have been made with respect to the warrants or shares or alternatively, that the securities are "covered securities" under Section 18 of the Securities Act; and (b) validly issued, fully paid and non-assessable.

3. Terms and Exercise of Warrants.

3.1. Exercise Price. Each Warrant shall entitle the Holder, subject to the provisions of the applicable Warrant Certificate and of this Warrant Agency Agreement, to purchase from the Company the number of shares of Common Stock, stated therein, at the exercise price of \$[] per share, subject to the subsequent adjustments provided by Section 4 hereof and Section 3 of the Warrant Certificates. The term "Exercise Price" as used in this Warrant Agency Agreement refers to the price per share at which shares of Common Stock, may be purchased at the time a Warrant is exercised.

3.2. Duration of Warrants. The Warrants have a three-year term and may be exercised only during the period ("Exercise Period") commencing on or after [] and ending on 5:00 p.m. (New York City time) on [] (the "Termination Date"). Each Warrant not exercised before 5:00 p.m. (New York City time) on the Termination Date shall become void, and, subject to Sections 7.11 and 9.5 hereof, all rights thereunder and all rights in respect thereof under this Warrant Agency Agreement shall cease at the close of business on the Termination Date.

3.3. Exercise of Warrants.

3.3.1. Exercise and Payment. (a) Subject to the provisions of this Warrant Agency Agreement, a Holder of a Definitive Certificate may exercise Warrants evidenced by such Definitive Certificate by delivering to the Warrant Agent and the Company, a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed to the Warrant Certificate. Notwithstanding any other provision in this Warrant Agency Agreement, a holder whose interest in a Warrant is a beneficial interest in a Global Certificate held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable). Any Holder exercising a Warrant shall deliver payment of the Exercise Price pursuant to Section 2(a) and Section 2(b) of the Warrant Certificate set forth in Exhibit B attached hereto. The Warrant Agent shall forward funds received for Warrant exercises by the fifth Business Day of the following month after such funds are received by the Warrant Agent by wire transfer to an account designated by the Company. The Company acknowledges that the bank accounts maintained by the Warrant Agent in connection with the services provided under this Warrant Agency Agreement will be in Equiniti's name, as agent for the Company, and that the Warrant Agent may receive investment earnings in connection with the investment at Warrant Agent risk and for its benefit of funds (the "Funds") held in those accounts from time to time. Until paid pursuant to the terms of this Warrant Agency Agreement, Equiniti will hold the Funds through such accounts in: deposit accounts of commercial banks with Tier 1 capital exceeding \$1 billion or with an average rating above investment grade by S&P (LT Local Issuer Credit Rating), Moody's (Long Term Rating) and Fitch Ratings, Inc. (LT Issuer Default Rating) (each as reported by Bloomberg Finance L.P.). Equiniti shall have no responsibility or liability for any diminution of the Funds that may result from any deposit made by Equiniti in accordance with this paragraph, including any losses resulting from a default by any bank, financial institution or other third party. Equiniti may from time to time receive interest, dividends or other earnings in connection with such deposits. Equiniti shall not be obligated to pay such interest, dividends or earnings to the Company, any holder or any other party. If either the Exercise

Note or the Exercise price relating to an exercise are received or deemed to be received after the Termination Date, the exercise thereof will be null and void and any funds delivered to the Company will be returned to the Holder or Participant, as the case may be, as soon as practicable. In no event will interest accrue on any funds deposited with the Company in respect of an exercise or attempted exercise of the Warrants. (b) The Warrants shall cease to be exercisable and shall terminate and become void and callable as set forth in the applicable Warrant Certificate. The Company hereby instructs the Warrant Agent to record cost basis for newly issued shares in a manner to be subsequently communicated by the Company in writing to the Warrant Agent.

3.3.2. Issuance of Warrant Shares.

(a) The Warrant Agent shall, as promptly as practicable following the date of exercise of any Warrant, advise the Company (to the extent known the Warrant Agent) and the transfer agent and registrar for the Company's Common Stock, which on the date hereof is Equiniti Trust Company, LLC (the "Transfer Agent"), in respect of (i) the number of Warrant Shares indicated on the Notice of Exercise as issuable upon such exercise with respect to such exercised Warrants, (ii) the instructions of the Holder or Participant, as the case may be, provided to the Warrant Agent with respect to the delivery of the Warrant Shares and the number of Warrants that remain outstanding after such exercise, and (iii) such other information as the Company or the Transfer Agent shall reasonably request.

(b) Upon the Warrant Agent's receipt, at or prior to the Close of Business on the Termination Date set forth in a Warrant Certificate, of the executed Notice of Exercise, accompanied by payment of the Exercise Price pursuant to Section 2(a) and 2(b) of the Warrant Certificate set forth in Exhibit B attached hereto, the Warrant Agent shall cause the Warrant Shares underlying such Warrant to be delivered by the Transfer Agent to or upon the order of the Holder of such Warrant, registered in such name or names as may be designated by such Holder, no later than the Warrant Share Delivery Date. If the Company is then a participant in DTC's Deposit or Withdrawal at Custodian ("DWAC") system and there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder, then the Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's account with DTC through its Deposit or Withdrawal at Custodian system.

3.3.3. Valid Issuance. All Warrant Shares issued by the Company upon the proper exercise of a Warrant in conformity with this Warrant Agency Agreement shall be validly issued, fully paid and non-assessable.

3.3.4. No Fractional Shares or Scrip. Notwithstanding any provision to the contrary contained in this Agreement or the Warrant, the Company shall not be required to issue any fraction of a Warrant Share or scrip representing fractional shares upon the exercise of the Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price of the Common Stock or round up to the next whole share. Accordingly, a holder of a Warrant is entitled to exercise a number of Warrants that would result solely in the holder receiving one or more whole Warrant Shares. Prior to paying an adjustment in cash in respect of a fractional interest, the Company shall first provide to Equiniti an initial funding of one thousand dollars (\$1,000) for the purpose of issuing cash in lieu of fractional shares. From time to time thereafter, Equiniti may request additional funding to cover fractional payments. Equiniti shall have no obligation to make fractional payments unless the Company shall have provided the necessary funds to pay in full all amounts due and payable with respect thereto.

3.3.5. Charges, Taxes, and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, the Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached to the Warrant properly completed and duly executed by the Holder and accompanied by a signature guarantee and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto; and (the Company shall use its best efforts to pay, or procure payment of issue or stamp taxes levied in connection with the issuance of the Warrant or Warrant Shares to the Holder (“Relevant Taxes”). The Holder agrees to cooperate with the Company and provide all necessary and reasonable information and documentation to the Company in a timely manner (and in any event within 10 Business Days of request) to enable the Company to procure payment of any Relevant Taxes and facilitate the making of any necessary filings in respect of Relevant Taxes required to be made within applicable time limits. The Company shall not be liable for any Relevant Taxes or any penalty, fine, surcharge, interest, charge, cost or other similar imposition arising in respect of Relevant Taxes to the extent that such amount arises or is increased as a result of any failure by a Holder to timely provide the Company with any information or documentation reasonably requested pursuant to Section 2(d)(vi) of the Warrant Certificate set forth in Exhibit B attached hereto. The Company shall pay all Transfer Agent fees required for processing of any Notice of Exercise and all fees to DTC (or another established clearing corporation performing similar functions) required for electronic delivery of the Warrant Shares.

3.3.6. Date of Issuance. The Company will treat an exercising Holder as a beneficial owner of the Warrant Shares as of the date of exercise of any Warrant, except that, if such date of exercise is a date when the stock transfer books of the Company are closed, such person shall be deemed to have become the holder of such shares at the open of business on the next succeeding date on which the stock transfer books are open.

3.3.7. [Reserved].

3.3.8. [Reserved].

3.3.9. Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the number of Warrant Shares issuable in connection with any exercise, the Company shall promptly deliver to the Holder the number of Warrant Shares that are not disputed.

4. Adjustments. The Exercise Price, the number of shares of Common Stock covered by each Warrant and the number of Warrants outstanding are subject to adjustment from time to time as provided in Section 3 of the Warrant Certificate set forth in Exhibit B attached hereto. The Company hereby agrees that it will provide the Warrant Agent with reasonable notice of any such adjustments. The Warrant Agent shall have no obligation under any Section of this Agreement to determine whether an event resulting in any such adjustment has occurred or to calculate any of the adjustments set forth herein. All Warrants originally issued by the Company subsequent to any adjustment made to the Exercise Price pursuant to the Warrant shall evidence the right to purchase, at the adjusted Exercise Price, the number of shares of Common Stock, purchasable from time to time hereunder upon exercise of the Warrants, all subject to further adjustment as provided herein. Whenever the Exercise Price or the number of Warrant Shares issuable upon the exercise of each Warrant is adjusted, the Company shall (a) promptly prepare a certificate setting forth the Exercise Price of each Warrant as so adjusted and the increase or decrease, if any, in the number of Warrant Shares purchasable at such price upon the exercise of a Warrant, and a brief statement of the facts accounting for such adjustment, (b) promptly file with the Warrant Agent and with the Transfer Agent a copy of such certificate and (c) instruct the Warrant Agent to send a brief summary thereof to each Holder of a Warrant. If the Company requests the Warrant Agent to send such notices, it shall provide the Warrant Agent with a draft notice to be used for this purpose. The Warrant Agent shall be entitled to rely conclusively on, and shall be fully protected in relying on, any certificate, notice or instructions provided by the Company with respect to any adjustment of the Exercise Price or the number of shares issuable upon exercise of a Warrant, or any related matter, and the Warrant Agent shall not be liable for any action taken, suffered or omitted to be taken by it in accordance with any such certificate, notice or instructions or pursuant to this Warrant Agency Agreement. The Warrant Agent shall not be deemed to have knowledge of any such adjustment unless and until it shall have received written notice thereof from the Company.

5. Restrictive Legends; Fractional Warrants. In the event that a Warrant Certificate surrendered for transfer bears a restrictive legend, the Warrant Agent shall not register that transfer until the Warrant Agent has received an opinion of counsel for the Company stating that such transfer may be made and indicating whether the Warrants must also bear a restrictive legend upon that transfer. The Company shall not issue fractions of Warrants or distribute a Global Certificate or Warrant Certificates that evidence fractional Warrants. Whenever any fractional Warrant would otherwise be required to be issued or distributed, the actual issuance or distribution shall be paid via a cash adjustment as set forth in Section 3.3.4 of this Agreement. The Warrant Agent shall not be required to effect any registration of transfer or exchange which will result in the transfer of or delivery of a Warrant Certificate for a fraction of a Warrant. The Company shall not issue fractions of shares of Common Stock upon exercise of Warrants or distribute stock certificates that evidence fractional shares of Common Stock. Whenever any fraction of a share of Common Stock would otherwise be required to be issued or distributed, the actual issuance or distribution in respect thereof shall be made in accordance with Section 2(d)(v) of the Warrant Certificate attached hereto as Exhibit B.

6. Other Provisions Relating to Rights of Holders of Warrants.

6.1. No Rights as Stockholder. Except as otherwise specifically provided herein and in accordance with the Warrant Certificates, a Holder, solely in his, her or its capacity as a holder of Warrants, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant Agency Agreement be construed to confer upon a Holder, solely in its capacity as the registered holder of Warrants, any of the rights of a shareholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of share capital, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights or rights to participate in new issues of shares, or otherwise, prior to the issuance to the Holder of the Warrant Shares which it is then entitled to receive upon the due exercise of Warrants.

6.2. Reservation of Common Stock. The Company shall at all times reserve and keep available a number of its authorized but unissued shares of Common Stock pursuant to this Agreement and Section 6(d) of the Warrant Certificate attached hereto as Exhibit B.

7. Conditions of the Warrant Agent's Obligations. The Warrant Agent accepts its obligations herein set forth upon the express terms and conditions hereof, including the following to all of which the Company agrees and to all of which the rights hereunder of the Holders from time to time shall be subject:

7.1. Compensation and Indemnification. The Company agrees promptly to pay the Warrant Agent the compensation set forth in a mutually agreed upon fee schedule executed on or before the date hereof for all services rendered by the Warrant Agent and on demand of the Warrant Agent to reimburse the Warrant Agent for reasonable out-of-pocket expenses (including reasonable counsel fees) and other disbursements incurred in the preparation, delivery, negotiation, amendment, administration and execution of this Warrant Agency Agreement and the exercise and performance of its duties hereunder. The Company covenants and agrees to indemnify and to hold harmless the Rights Agent against, any and all loss, liability, damage, judgment, fine, penalty, claim, demand, settlement, cost or expense (including, without limitation, the reasonable and documented fees and expenses of legal counsel) that may be paid, incurred or suffered by it, or which it may become subject, without gross negligence, bad faith or willful misconduct on the part of the Warrant Agent (which gross negligence, bad faith, or willful misconduct must be determined by a final, non-appealable judgment of a court of competent jurisdiction), for any action taken, suffered, or omitted to be taken by the Warrant Agent in connection with the execution, acceptance, administration, exercise and performance of its duties under this Warrant Agency Agreement, including the reasonable and documented costs and expenses of defending against any claim of liability arising therefrom, directly or indirectly, or enforcing its rights hereunder. The Warrant Agent shall not be liable for the Company's failure to timely deliver Warrant Shares pursuant to the terms of the Warrants, nor shall the Warrant Agent be liable for any liquidated damages or any other damages associated therewith.

7.2. Agent for the Company. In acting under this Warrant Agency Agreement and in connection with the Warrant Certificates, the Warrant Agent is acting solely as agent of the Company and does not assume any obligations or relationship of agency or trust for or with any of the Holders of Warrant Certificates or beneficial owners of Warrants.

7.3. Counsel. The Warrant Agent may consult with counsel satisfactory to it, which may include counsel for the Company, and the advice or opinion of such counsel shall be full and complete authorization and protection to the Warrant Agent, and the Warrant Agent shall have no liability for or in respect of any action taken, suffered or omitted by it hereunder in the absence of bad faith and in accordance with the advice or opinion of such counsel.

7.4. Documents. From time to time, Company may provide Warrant Agent with instructions concerning the services performed by the Warrant Agent hereunder. The Warrant Agent and its agents and subcontractors shall be protected and shall incur no liability for or in respect of any action taken or omitted to be taken, suffered by it in reliance upon any Warrant Certificate, notice, direction, consent, certificate, affidavit, statement or other paper or document reasonably believed by it to be genuine and to have been presented or signed by the proper parties. The Warrant Agent shall not be held to have notice of any change of authority of any person, until receipt of written notice thereof from Company.

7.5. Certain Transactions. The Warrant Agent, and its officers, directors and employees, may become the owner of, or acquire any interest in, Warrants, with the same rights that it or they would have if it were not the Warrant Agent hereunder, and, to the extent permitted by applicable law, it or they may engage or be interested in any financial or other transaction with the Company and may act on, or as depository, trustee or agent for, any committee or body of Holders of Warrant Securities or other obligations of the Company as freely as if it were not the Warrant Agent hereunder. Nothing in this Warrant Agency Agreement shall be deemed to prevent the Warrant Agent from acting as trustee under any indenture to which the Company is a party. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

7.6. No Liability for Interest. Unless otherwise agreed with the Company, the Warrant Agent shall have no liability for interest on any monies at any time received by it pursuant to any of the provisions of this Warrant Agency Agreement or of the Warrant Certificates.

7.7. No Liability for Invalidity. The Warrant Agent shall not be under any responsibility in respect of the validity of this Warrant Agency Agreement or the execution and delivery hereof (except the due execution hereof by the Warrant Agent) or in respect of the validity or execution of any Warrant Certificate (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Warrant Agency Agreement or in any Warrant Certificate; nor shall it be responsible for the adjustment of the Exercise Price or the making of any change in the number of shares of Common Stock required under the provisions of Section 4 (Adjustments) or Sections 5 and 3.3.4 regarding fractional shares or responsible for the manner, method or amount of any such change or the ascertaining of the existence of facts that would require any such adjustment or change (except with respect to the exercise of Warrants evidenced by Warrant Certificates after actual notice of any adjustment of the Exercise Price); nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock to be issued pursuant to this Warrant Agency Agreement or any Warrant Certificate or as to whether any shares of Common Stock will, when issued, be duly authorized, validly issued, fully paid and nonassessable.

7.8. No Responsibility for Representations. The Warrant Agent shall not be responsible for any of the recitals, statement of facts or representations herein or in the Warrant Certificates (except as to the Warrant Agent's countersignature thereon), all of which are made solely by the Company.

7.9. No Implied Obligations. The Warrant Agent shall be obligated to perform only such duties as are herein and in the Warrant Certificates specifically set forth and no implied duties or obligations shall be read into this Warrant Agency Agreement or the Warrant Certificates against the Warrant Agent. The Warrant Agent shall not be under any obligation to take any action hereunder which may tend to involve it in any expense or liability, the payment of which within a reasonable time or adequate indemnification is not, in its reasonable opinion, assured to it. The Warrant Agent shall not be accountable or under any duty or responsibility for the use by the Company of any of the Warrant Certificates authenticated by the Warrant Agent and delivered by it to the Company pursuant to this Warrant Agency Agreement or for the application by the Company of the proceeds of the Warrant Certificates. The Warrant Agent shall have no duty or responsibility in case of any default by the Company in the performance of its covenants or agreements contained herein or in the Warrant Certificates or in the case of the receipt of any written demand from a Holder of a Warrant Certificate with respect to any action or default by the Company, including, without limiting the generality of the foregoing, any duty or responsibility to initiate or attempt to initiate any proceedings at law.

7.10. Signature Guarantee. A party requesting transfer of Warrants or the Warrant Shares must provide any evidence of authority that may be required by the Warrant Agent, including but not limited to, a signature guarantee from an eligible guarantor institution participating in a signature guarantee program approved by the Securities Transfer Association.

7.11. Survival. Notwithstanding anything contained herein to the contrary, the rights and obligations of the parties set forth in this Section 7 shall survive the exercise or expiration of the Warrants, the termination of this Warrant Agency Agreement and the resignation, replacement or removal of the Warrant Agent.

7.12. Limitation of Liability. Neither party to this Warrant Agency Agreement shall be liable to the other party for any consequential, indirect, special or incidental damages under any provisions of this Warrant Agency Agreement or for any consequential, indirect, punitive, special or incidental damages arising out of any act or failure to act hereunder even if that party has been advised of or has foreseen the possibility of such damages. Notwithstanding anything contained herein to the contrary, the Warrant Agent's aggregate liability during any term of this Warrant Agency Agreement with respect to, arising from, or arising in connection with this Warrant Agency Agreement, or from all services provided or omitted to be provided under this Warrant Agency Agreement, whether in contract, or in tort, or otherwise, is limited to, and shall not exceed, the amounts paid hereunder by the Company to Warrant Agent as fees and charges, but not including reimbursable expenses, during the twelve (12) months immediately preceding the event for which recovery from Warrant Agent is being sought.

8. Purchase or Consolidation or Change of Name of Warrant Agent.

8.1. Any Person into which the Warrant Agent or any successor Warrant Agent may be merged or with which it may be consolidated, or any Person resulting from any merger or consolidation to which the Warrant Agent or any successor Warrant Agent shall be party, or any Person succeeding to the corporate trust, stock transfer or shareholder services business of the Warrant Agent or any successor Warrant Agent, shall be the successor to the Warrant Agent under this Warrant Agency Agreement without the execution or filing of any paper or any further act on the part of any of the parties hereto, provided that such Person would be eligible for appointment as a successor Warrant Agent under the provisions of Section 9 of this Warrant Agency Agreement. In case at the time such successor Warrant Agent shall succeed to the agency created by this Warrant Agency Agreement any of the Warrant Certificates shall have been countersigned but not delivered, any such successor Warrant Agent may adopt the countersignature of the predecessor Warrant Agent and deliver such Warrant Certificates so countersigned; and in case at that time any of the Warrant Certificates shall not have been countersigned, any successor Warrant Agent may countersign such Warrant Certificates either in the name of the predecessor Warrant Agent or in the name of the successor Warrant Agent; and in all such cases such Warrant Certificates shall have the full force provided in the Warrant Certificates and in this Warrant Agency Agreement.

8.2. In case at any time the name of the Warrant Agent shall be changed and at such time any of the Warrant Certificates shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Warrant Certificates so countersigned; and in case at that time any of the Warrant Certificates shall not have been countersigned, the Warrant Agent may countersign such Warrant Certificates either in its prior name or in its changed name; and in all such cases such Warrant Certificates shall have the full force provided in the Warrant Certificates and in this Warrant Agency Agreement.

9. Duties of Warrant Agent. The Warrant Agent undertakes the duties and obligations imposed by this Warrant Agency Agreement upon the following express terms and conditions (and no implied duties or obligations shall be read into this Warrant Agency Agreement against the Warrant Agent), by all of which the Company, by its acceptance hereof, shall be bound:

9.1. Whenever in the performance of its duties under this Warrant Agency Agreement, the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a certificate signed by the Chief Executive Officer, Chief Financial Officer, General Counsel or Secretary of the Company; and such certificate shall be full authentication to the Warrant Agent and the Warrant Agent shall be fully protected and shall not incur no liability for any action taken, suffered or omitted to be taken by it under the provisions of this Warrant Agency Agreement in reliance upon such certificate in the absence of bad faith.

9.2. Subject to the limitation set forth in Section 7.12 of this Warrant Agency Agreement, the Warrant Agent shall be liable hereunder only for its own gross negligence, bad faith or willful misconduct (which gross negligence, bad faith, or willful misconduct must be determined by a final, non-appealable judgment of a court of competent jurisdiction).

9.3. The Warrant Agent is hereby authorized to accept instructions with respect to the performance of its duties hereunder from the Chief Executive Officer, Chief Financial Officer, General Counsel or Secretary of the Company, and to apply to such officers for advice or instructions with respect to any matter arising in connection with the services to be performed by the Warrant Agent under this Warrant Agency Agreement, and it shall not be liable and shall be indemnified and held harmless by the Company for any action taken, suffered or omitted to be taken by it in the absence of bad faith in accordance with instructions of any such officer, provided Warrant Agent carries out such instructions without gross negligence, bad faith or willful misconduct (which gross negligence, bad faith or willful misconduct must be determined by a final, non-appealable judgement of a court of competent jurisdiction).

9.4. The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorney or agents, and the Warrant Agent shall not be answerable or accountable for any act, default, neglect or misconduct of any such attorney or agents or for any loss to the Company resulting from any such act, default, neglect or misconduct, provided reasonable care was exercised in the selection and continued employment thereof.

9.5. This Section 9 shall survive the exercise or expiration of the Warrants, the termination of this Warrant Agency Agreement and the resignation, replacement or removal of the Warrant Agent.

10. Change of Warrant Agent. The Warrant Agent, or any successor to it hereafter appointed, may resign and be discharged from its duties under this Warrant Agency Agreement upon 30 days' notice in writing sent to the Company, and in the event that the Warrant Agent or one of its affiliates is not also the transfer agent for the Common Stock, to each transfer agent of the Common Stock known to the Warrant Agent, and to the Holders of record of the Warrant Certificates. In the event the transfer agency relationship in effect between the Company and the Warrant Agent terminates, the Warrant Agent will be deemed to have resigned automatically and be discharged from its duties under this Warrant Agency Agreement as of the effective date of such termination, and the Company shall be responsible for sending any required notice. The Company may remove the Warrant Agent or any successor Warrant Agent upon 30 days' notice in writing, sent to the Warrant Agent or successor Warrant Agent, as the case may be, and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or by the Holder of a Warrant Certificate (who shall, with such notice, submit his Warrant Certificate for inspection by the Company), then the Holder of any Warrant Certificate may apply to any court of competent jurisdiction for the appointment of a new Warrant Agent, provided that, for purposes of this Warrant Agency Agreement, the Company shall be deemed to be the Warrant Agent until a new warrant agent is appointed. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be an entity organized and doing business under the laws of the United States or of a state thereof, in good standing, which is authorized under such laws to exercise stock transfer powers and is subject to supervision or examination by federal or state authority and which has at the time of its appointment as Warrant Agent a combined capital and surplus (together with its affiliates) of at least \$50,000,000. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed; but the predecessor Warrant Agent shall deliver and transfer to the successor Warrant Agent any property at the time held by it hereunder and execute and deliver, at the expense of the Company, any further assurance, conveyance, act or deed necessary for such purpose without assumption of any liability on the part of the former Warrant Agent. Not later than the effective date of any such appointment, the Company shall file notice thereof in writing with the predecessor Warrant Agent and each transfer agent of the Common Stock, and mail or other deliver a notice thereof in writing to the Holders of the Warrant Certificates. However, failure to give any notice provided for in this Section 9, or any defect therein, shall not affect the legality or validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

11. Issuance of New Warrant Certificates. Notwithstanding any of the provisions of this Warrant Agency Agreement or of the Warrants to the contrary, the Company may, at its option, issue new Warrant Certificates evidencing Warrants in such form as may be approved by its Board of Directors to reflect any adjustment or change in the Exercise Price per share and the number or kind or class of shares of stock or other securities or property purchasable under the several Warrant Certificates made in accordance with the provisions of this Warrant Agency Agreement.

12. Notices. Notices or demands authorized by this Warrant Agency Agreement to be given or made (i) by the Warrant Agent or by the Holder of any Warrant Certificate to or on the Company, (ii) subject to the provisions of Section 10, by the Company or by the Holder of any Warrant Certificate to or on the Warrant Agent or (iii) by the Company or the Warrant Agent to the Holder of any Warrant Certificate, shall be deemed given (a) on the date delivered, if delivered personally, (b) when deposited with Federal Express or another recognized overnight courier, if sent by Federal Express or another recognized overnight courier, (c) when mailed with postage prepaid, if mailed by registered or certified mail (return receipt requested), and (d) the date of transmission, if such notice or communication is delivered via facsimile (with confirmation) or email attachment (other than to the Warrant Agent) at or prior to 5:30 p.m. (New York City time) on a Business Day and (e) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile (with confirmation) or email attachment (other than to the Warrant Agent) on a day that is not a Business Day or later than 5:30 p.m. (New York City time) on any Business Day, in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

12.1. Notice Information.

If to the Company, to:

Nuwellis, Inc.

12988 Valley View Road
Eden Prairie, Minnesota 55344
Attention: Robert B. Scott
Chief Financial Officer
Email: robert.scott@nuwellis.com

If to the Warrant Agent, to:

Equiniti Trust Company, LLC
48 Wall Street, 22nd Floor
New York, New York 10005
Attention: Corporate Actions - Warrants
Email: ReorgWarrants@equiniti.com

Notwithstanding anything to the contrary herein, for any notice delivered by email to be deemed given or made, such notice must be followed by notice sent by overnight courier service to be delivered on the next business day following such email, unless the recipient of such email has acknowledged via return email receipt of such email.

12.2. If to the Holder of any Warrant Certificate, to the address of such Holder as shown on the registry books of the Company. Any notice required to be delivered by the Company to the Holder of any Warrant may be given by the Warrant Agent on behalf of the Company. Notwithstanding any other provision of this Warrant Agency Agreement, where this Warrant Agency Agreement provides for notice of any event to a Holder of any Warrant, such notice shall be sufficiently given if given to the Depository (or its designee) pursuant to the procedures of the Depository or its designee.

13. Supplements and Amendments.

13.1. The Company and the Warrant Agent may from time to time supplement or amend this Warrant Agency Agreement without the approval of any Holders of Warrants in order to: (a) add to the covenants and agreements of the Company for the benefit of the Holders of the Warrants or to surrender any rights or power reserved to or conferred upon the Company in this Warrant Agency Agreement; or (b) to cure any ambiguity, to correct or supplement any provision contained herein which may be defective or inconsistent with any other provisions herein, or to make any other provisions with regard to matters or questions arising hereunder which the Company and the Warrant Agent may deem necessary or desirable; provided that such addition or surrender or such change shall not adversely affect the interests of the Holders of the Warrants in any material respect.

13.2. In addition to the foregoing, with the consent of Holders of Warrants entitled, upon exercise thereof, to receive not less than a majority of the shares of Warrant Shares issuable thereunder, the Company and the Warrant Agent may modify this Warrant Agency Agreement for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Warrant Agency Agreement or modifying in any manner the rights of the Holders of the Warrants; provided, however, that no modification of the terms (including but not limited to the adjustments described in Section 4) upon which the Warrants are exercisable or reducing the percentage required for consent to modification of this Warrant Agency Agreement may be made without the consent of the Holder of each outstanding Warrant affected thereby. As a condition precedent to the Warrant Agent's execution of any amendment, the Company shall deliver to the Warrant Agent a certificate from a duly authorized officer of the Company that states that the proposed amendment complies with the terms of this Section 13.

14. Successors. All covenants and provisions of this Warrant Agency Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns hereunder.

15. Benefits of this Warrant Agency Agreement. Nothing in this Warrant Agency Agreement shall be construed to give any Person other than the Company, the Holders of Warrants and the Warrant Agent any legal or equitable right, remedy or claim under this Warrant Agency Agreement; but this Warrant Agency Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the Holders of the Warrants.

16. Governing Law. This Warrant Agency Agreement and each Warrant issued hereunder shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to the conflicts of law principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of or relating in any way to this Warrant Agency Agreement shall be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and the appellate courts thereof, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenience forum.

17. Severability. This Warrant Agency Agreement shall be deemed severable, and the invalidity or unenforceability of any term or provision hereof shall not affect the validity or enforceability of this Warrant Agency Agreement or of any other term or provision hereof. Furthermore, in lieu of any such invalid or unenforceable term or provision, the parties hereto intend that there shall be added as a part of this Warrant Agency Agreement a provision as similar in terms to such invalid or unenforceable provision as may be possible and be valid and enforceable. If an invalid or unenforceable provision shall affect the rights, immunities, liabilities, duties or obligations of the Warrant Agent, the Warrant Agent shall be entitled to resign immediately upon written notice to the Company.

18. Force Majeure. Notwithstanding anything to the contrary contained herein, the Warrant Agent will not be liable for any delays or failures in performance resulting from acts beyond its reasonable control including, without limitation, acts of God, pandemics, epidemics, terrorist acts, shortage of supply, breakdowns or malfunctions, interruptions or malfunction of computer facilities, or loss of data due to power failures or mechanical difficulties with information storage or retrieval systems, labor difficulties, war, or civil unrest.

19. Confidentiality. The Warrant Agent and the Company agree that all books, records, information and data pertaining to the business of the other party, including inter alia, personal, non-public Holder information, which are exchanged or received pursuant to the negotiation or the carrying out of this Warrant Agency Agreement including the compensation for services performed hereunder shall remain confidential, and shall not be voluntarily disclosed to any other person, except as may be required by law, including, without limitation, pursuant to subpoenas from state or federal government authorities (e.g., in divorce and criminal actions).

20. Miscellaneous Provisions.

20.1. Further Assurances. The Company shall perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered all such further and other acts, instruments and assurances as may reasonably be required by the Warrant Agent for the carrying out or performing by any party of the provisions of this Warrant Agency Agreement.

20.2. Examination of the Warrant Agreement. A copy of this Warrant Agency Agreement shall be available at all reasonable times at the office of the Warrant Agent designated for such purpose for inspection by any Holder. Prior to such inspection, the Warrant Agent may require any such holder to provide reasonable evidence of its interest in the Warrants.

20.3. Counterparts. This Warrant Agency Agreement may be executed in any number of original, facsimile or electronic counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

20.4. Effect of Headings. The Section headings herein are for convenience only and are not part of this Warrant Agency Agreement and shall not affect the interpretation thereof.

21. Certain Definitions. As used herein, the following terms shall have the following meanings:

21.1. "Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

21.2. "Warrant Share Delivery Date" means the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company and the Warrant Agent of the Notice of Exercise, provided that payment of the aggregate Exercise Price is received by the Warrant Agent one (1) Trading Day prior to such second Trading Day after the delivery of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Warrant Agent and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company and Warrant Agent of the Notice of Exercise, provided that payment of the aggregate Exercise Price is received by the Warrant Agent one (1) Trading Day prior to such second Trading Day after the delivery of the Notice of Exercise.

21.3. "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

21.4. "Trading Day" means any day on which the Common Stock is traded on the Trading Market.

21.5. "Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

[Signature Page to Follow]

IN WITNESS WHEREOF, this Warrant Agency Agreement has been duly executed by the parties hereto as of the day and year first above written.

NUWELLIS, INC.

By: _____

Name: Nestor Jaramillo, Jr.

Title: Chief Executive Officer

EQUINITI TRUST COMPANY, LLC,
as the Warrant Agent

By: _____

Name:

Title:

ANNEX A

FEE SCHEDULE

Acceptance Fee	\$5,000.00
Monthly Fee	\$500.00
Per Exercise Fee	\$50.00

OUT-OF-POCKET EXPENSES

All customary out-of-pocket expenses will be billed in addition to the foregoing fees.

The foregoing fees apply to services ordinarily rendered by EQ as Warrant Agent and do not include any fees associated with voluntary or mandatory redemptions on the issued warrants. Fees are subject to reasonable adjustment based on final review of documents or changes in responsibilities.

WARRANT CERTIFICATE REQUEST NOTICE

To: Equiniti Trust Company, LLC, as Warrant Agent for Nuwellis, Inc. (the "Company")

The undersigned Holder of Preferred Stock Purchase Warrants ("Warrants") in the form of Global Certificates issued by the Company hereby elects to receive a Definitive Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Certificates:
2. Name of Holder in Definitive Certificate (if different from name of Holder of Warrants in form of Global Certificates):
3. Number of Warrants in name of Holder in form of Global Certificates:

4. Number of Warrants for which Definitive Certificate shall be issued:

5. Number of Warrants in name of Holder in form of Global Certificates after issuance of Definitive Certificate, if any: _____
6. Definitive Certificate shall be delivered to the following address:

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Definitive Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Certificates in the name of the Holder equal to the number of Warrants evidenced by the Definitive Certificate.

[SIGNATURE OF HOLDER]

Name of Investing Entity:

Signature of Authorized Signatory of Investing Entity:

Name of Authorized Signatory:

Title of Authorized Signatory:

Date:

EXHIBIT A

FORM OF GLOBAL WARRANT CERTIFICATE OF
WARRANT TO COMMON STOCK

UNLESS THIS CERTIFICATE IS PRESENTED BY AN AUTHORIZED REPRESENTATIVE OF THE DEPOSITORY TRUST COMPANY, A NEW YORK CORPORATION (“DTC”), TO ISSUER OR ITS AGENT FOR REGISTRATION OF TRANSFER, EXCHANGE, OR PAYMENT, AND ANY CERTIFICATE ISSUED IS REGISTERED IN THE NAME OF CEDE & CO. OR IN SUCH OTHER NAME AS IS REQUESTED BY AN AUTHORIZED REPRESENTATIVE OF DTC (AND ANY PAYMENT IS MADE TO CEDE & CO. OR TO SUCH OTHER ENTITY AS IS REQUESTED BY AN AUTHORIZED REPRESENTATIVE OF DTC), ANY TRANSFER, PLEDGE, OR OTHER USE HEREOF FOR VALUE OR OTHERWISE BY OR TO ANY PERSON IS WRONGFUL INASMUCH AS THE REGISTERED OWNER HEREOF, CEDE & CO., HAS AN INTEREST HEREIN.

Certificate No.: 1
Number of Warrants: []

CUSIP No.: []
Issue Date: []

NUWELLIS, INC.
GLOBAL WARRANT CERTIFICATE
NOT EXERCISABLE AFTER []

This certifies that CEDE & CO., or its registered assigns, is the registered owner of the number of Warrants set forth above (the “**Warrants**”). Each Warrant entitles its registered holder to purchase from Nuwellis, Inc., a Delaware corporation (the “**Company**”), at any time prior to 5:00 P.M. (New York City time) on [], one share of Common Stock, par value \$0.0001 per share, of the Company (each, a “**Warrant Share**” and collectively, the “**Warrant Shares**”), at an exercise price of \$[] per share, subject to possible adjustments as provided in the Warrant Agency Agreement (as defined below) and the Warrant Certificate in the form of Exhibit A attached to this Global Warrant Certificate (the “**Warrant Certificate**”).

The terms and conditions of the Warrants and the rights and obligations of the holder of this Global Warrant Certificate are set forth in the Warrant Certificate and the Warrant Agency Agreement, dated as of [] (the “**Warrant Agency Agreement**”) between the Company and Equiniti Trust Company, LLC (the “**Warrant Agent**”), which Warrant Certificate and Warrant Agency Agreement are each hereby incorporated by reference in and made a part of this Global Warrant Certificate. A copy of the Warrant Agency Agreement is available for inspection during business hours at the office of the Warrant Agent. Defined terms used in this Global Warrant Certificate but not defined herein shall have the meanings given to them in the Warrant Certificate or Warrant Agency Agreement. In the event of any discrepancy or inconsistency between the terms and conditions of the Warrant Certificate and the Warrant Agency Agreement, the terms and conditions of the Warrant Certificate shall prevail, govern and control.

The Company and the Warrant Agent may deem and treat the registered Holder(s) hereof as the absolute owner(s) of this Global Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, of any distribution to the holder(s) hereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Neither the Warrants nor this Global Warrant Certificate entitles any holder hereof to any rights of a holder of Common Stock.

This Global Warrant Certificate shall not be valid or obligatory for any purpose until it shall have been countersigned by an authorized signatory of the Warrant Agent.

[Signature Page Follows]

NUWELLIS, INC.

By:

Name: Nestor Jaramillo, Jr.
Title: Chief Executive Officer

Dated: []

Countersigned:

EQUINITI TRUST COMPANY, LLC,
as Warrant Agent

By:

Name:
Title:

Exhibit A to Global Warrant Certificate

Warrant Certificate

(ATTACHED)

EXHIBIT B

**FORM OF DEFINITIVE WARRANT CERTIFICATE OF
WARRANT TO PURCHASE COMMON STOCK**

(ATTACHED)

January 30, 2024

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

Ladies and Gentlemen:

We have acted as counsel to Nuwellis, Inc., a Delaware corporation (the "**Company**"), in connection with the preparation and filing with the Securities and Exchange Commission (the "**Commission**") pursuant to the Securities Act of 1933, as amended (the "**Securities Act**"), of a Registration Statement on Form S-1 (File No. 333-276562) dated January 17, 2024 (as the same may be amended from time to time, the "**Registration Statement**"), relating to the offer and sale of (i) up to 16,326,530 units ("**Units**"), consisting of (A) 16,326,530 shares (the "**Shares**") of the Company's common stock, par value \$0.0001 per share (the "**Common Stock**") and (B) 16,326,530 immediately exercisable warrants (the "**Common Warrants**") to purchase 16,326,530 shares of Common Stock, (ii) up to 16,326,530 shares of Common Stock, issuable upon conversion of the Common Warrants (the "**Common Warrant Shares**"), and (iii) for some purchasers, in lieu of Shares, up to 16,326,530 pre-funded warrants (the "**Pre-Funded Warrants**" and together with the Common Warrants, the "**Warrants**") to purchase 16,326,530 shares of Common Stock (the "**Pre-Funded Warrant Shares**" and together with the Common Warrant Shares, the "**Warrant Shares**"). The Warrants are being issued pursuant to the terms of that certain warrant agency agreement (the "**Warrant Agency Agreement**") to be entered into by and among the Company and Equiniti Trust Company, LLC (the "**Warrant Agent**"), the form of which Warrant Agency Agreement has been filed as Exhibit 4.18 to the Registration Statement.

The Units, including the Shares and Common Warrants comprising such Units, are to be sold by the Company as described in the Registration Statement and pursuant to a placement agency agreement (the "**Placement Agency Agreement**") to be entered into by and between the Company, Lake Street Capital Markets, LLC and Maxim Group LLC, the form of which has been, or will be, filed as Exhibit 1.1 to the Registration Statement. We have assumed that the sale of the Units by the Company, including the Shares and Common Warrants comprising such Units, as described in the Registration Statement, the exercise price of the Warrants, will be at prices established by the Board of Directors of the Company or a duly-formed Pricing Committee thereof no less than the minimum prices authorized by the Board of Directors as of the date hereof, in accordance with the Delaware General Corporation Law. We have also assumed that, (i) the Warrant Shares will be properly delivered to the persons exercising the Warrants, and (ii) at the time of exercise of the Warrants, the consideration for the issuance and sale of the Warrant Shares in connection with such exercise is an amount that is not less than the par value of the Common Stock. With respect to the Warrant, we express no opinion to the extent that, notwithstanding the Company's current reservation of shares of Common Stock, future issuances of securities of the Company, including the Warrant Shares, and/or antidilution adjustments to outstanding securities of the Company, including the Warrants, may cause the Warrants to be exercisable for more shares of Common Stock than the number that then remain authorized but unissued and available for issuance.

For the purpose of rendering this opinion, we examined originals or copies of such documents as we deemed relevant. In conducting our examination, we assumed, without investigation, the genuineness of all signatures, the correctness of all certificates, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted as certified or photostatic copies, and the authenticity of the originals of such copies, and the accuracy and completeness of all records made available to us by the Company, including, but not limited to, the Certificate of Incorporation, the Warrants, the Placement Agency Agreement and the Warrant Agency Agreement. In addition, in rendering this opinion, we have assumed that the Units (including the Shares and Warrants included in the Units) and the shares of Warrant Shares issuable upon conversion of the Warrants, will be offered in the manner and on the terms identified or referred to in the Registration Statement, including all supplements and amendments thereto, the Placement Agency Agreement and the Warrant Agency Agreement. As to various questions of fact material to such opinions, we have relied upon statements or certificates of officials and representatives of the Company and others.

Our opinions are limited solely to matters set forth herein. The law covered by the opinions expressed herein is limited to New York law applicable to contracts and the Delaware General Corporate Law. We express no opinion as to whether the laws of any particular jurisdiction are applicable to the subject matter hereof. We are not rendering any opinion with respect to federal law, including federal securities laws, or state blue sky securities laws.

With regard to our opinions concerning the Units and Warrants, constituting valid and binding obligations of the Company:

1. Our opinions are subject to, and may be limited by, (a) applicable bankruptcy, reorganization, insolvency, moratorium, fraudulent transfer, voidable transaction, fraudulent conveyance, debtor and creditor, and other laws which relate to or affect creditors' rights generally, and (b) general principles of equity (including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law.
2. Our opinions are subject to the qualification that the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought.
3. We express no opinion as to any provision of the Units or Warrants that: (a) provides for liquidated damages, buy-in damages, monetary penalties, prepayment or make-whole payments or other economic remedies to the extent such provisions may constitute unlawful penalties, (b) relates to advance waivers of claims, defenses, rights granted by law, or notice, opportunity for hearing, evidentiary requirements, statutes of limitations, trial by jury, or procedural rights, (c) restricts non-written modifications and waivers, (d) provides for the payment of legal and other professional fees where such payment is contrary to law or public policy, (e) relates to exclusivity, election or accumulation of rights or remedies, (f) authorizes or validates conclusive or discretionary determinations, or (g) provides that provisions of the Warrants are severable to the extent an essential part of the agreed exchange is determined to be invalid and unenforceable.
4. We express no opinion as to whether a state court outside of the State of New York or a federal court of the United States would give effect to the choice of New York law or jurisdiction provided for in the Warrants.

Based on the foregoing, we are of the opinion that:

1. When the Warrants covered by the Registration Statement Units have been offered, sold, issued, duly executed and delivered by the Company as described in the Registration Statement and the related prospectus and in accordance with, and in the manner set forth in, the Placement Agency Agreement, the terms of the Warrants and the Warrant Agency Agreement (including, without limitation, the payment in full of all applicable consideration therefor), against payment therefor, such Warrants will constitute binding obligations of the Company.
2. The Common Stock covered by the Registration Statement and issuable upon exercise of the Warrants included in the Units, when they and such Warrants are offered, sold, issued and delivered by the Company as described in the Registration Statement and related prospectus and in accordance with, and in the manner set forth in, the Warrants, the Placement Agency Agreement and the Warrant Agency Agreement, including without limitation, the payment in full of all applicable consideration thereof, against payment therefor, will be validly issued, fully paid and non-assessable.

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

Very truly yours,

/s/ HONIGMAN LLP

HONIGMAN LLP

PDT/JMH/EAAL/JPK/GSWA

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

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "Agreement") is dated as of [____], 2024, between Nuwellis, Inc., a Delaware corporation (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to an effective registration statement under the Securities Act (as defined below), the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Acquiring Person" shall have the meaning ascribed to such term in Section 4.5.

"Action" shall have the meaning ascribed to such term in Section 3.1(j).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Applicable Laws" shall have the meaning ascribed to such term in Section 3.1(n).

"Authorizations" shall have the meaning ascribed to such term in Section 3.1(n).

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Unit Subscription Amount and (ii) the Company's obligations to deliver the Securities, in each case, have been satisfied or waived, but in no event later than the [second (2nd)] Trading Day following the date hereof.

"Commission" means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company that would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Common Unit” means each Common Unit consisting of one Share and one Common Warrant to purchase one Common Warrant Share.

“Common Unit Purchase Price” equals \$[] per each Common Unit, subject to adjustments for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of Common Stock that occur after the date of this agreement.

“Common Unit Subscription Amount” means, as to each purchaser, the aggregate amount to be paid for the Common Units hereunder as specified below such Purchaser’s name on the signature page of this Agreement and next to the heading “Common Unit Subscription Amount”, in immediately available funds.

“Common Warrants” means, collectively, the Common Stock purchase warrants delivered to the Purchasers at the Closing in accordance with Section 2.2(a) hereof, which Common Warrants shall be exercisable on the Closing Date and have a term of exercise equal to five (5) years from the initial exercise date, in the form of Exhibit A attached hereto.

“Common Warrant Shares” means the shares of Common Stock issuable upon exercise of the Common Warrants.

“Company Counsel” means Honigman LLP, with offices located at 650 Trade Centre Way, Suite 200, Kalamazoo, Michigan 49002.

“Disclosure Time” means, (i) if this Agreement is signed on a day that is not a Trading Day or after 9:00 a.m. (New York City time) and before midnight (New York City time) on any Trading Day, 9:01 a.m. (New York City time) on the Trading Day immediately following the date hereof, unless otherwise instructed as to an earlier time by the Placement Agents, and (ii) if this Agreement is signed between midnight (New York City time) and 9:00 a.m. (New York City time) on any Trading Day, no later than 9:01 a.m. (New York City time) on the date hereof, unless otherwise instructed as to an earlier time by the Placement Agents.

“Evaluation Date” shall have the meaning ascribed to such term in Section 3.1(s).

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“FCPA” means the Foreign Corrupt Practices Act of 1977, as amended.

“FDA” shall have the meaning ascribed to such term in Section 3.1(n).

“FDCA” shall have the meaning ascribed to such term in Section 3.1(n).

“FTC” shall have the meaning ascribed to such term in Section 3.1(n).

“GAAP” shall have the meaning ascribed to such term in Section 3.1(h).

“Indebtedness” shall have the meaning ascribed to such term in Section 3.1(aa).

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(p).

“Liens” means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

“Lock-Up Agreement” means the Lock-Up Agreement, dated as of the Closing Date, by and among the Company and the directors and officers of the Company, in a form reasonably acceptable to the Placement Agents.

“Material Adverse Effect” shall have the meaning assigned to such term in Section 3.1(b).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Placement Agency Agreement” means the Placement Agency Agreement by and between the Company and the Placement Agents dated the date hereof.

“Placement Agents” means Lake Street Capital Markets, LLC and Maxim Group LLC.

“Pre-Funded Units” means each Pre-Funded Unit consisting of one Pre-Funded Warrant to purchase one Pre-Funded Warrant Share and one Common Warrant to purchase one Common Warrant Share.

“Pre-Funded Unit Purchase Price” equals \$[] per each Pre-Funded Unit, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

“Pre-Funded Unit Subscription Amount” means, as to each Purchaser, the aggregate amount to be paid for the Pre-Funded Units purchased hereunder as specified below such Purchaser’s name on the signature page of this Agreement and next to the heading “Pre-Funded Unit Subscription Amount,” in immediately available funds.

“Pre-Funded Warrant” means, collectively, the Pre-Funded Common Stock purchase warrants delivered to the Purchasers at the Closing in accordance with Section 2.2(a) hereof, which Pre-Funded Warrants shall be exercisable immediately and shall expire when exercised in full, in the form of Exhibit B attached hereto.

“Pre-Funded Warrant Shares” means the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants.

“Preliminary Prospectus” means any preliminary prospectus included in the Registration Statement, as originally filed or as part of any amendment thereto or filed with the Commission pursuant to Rule 424(a) of the rules and regulations of the Commission under the Securities Act.

“Pricing Prospectus” means (i) the Preliminary Prospectus relating to the Securities that was included in the Registration Statement immediately prior to [] (New York City time) on the date hereof and (ii) any free writing prospectus (as defined in the Securities Act) identified on Schedule A hereto, taken together.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or, to the Company’s knowledge, threatened.

“Prospectus” means the final prospectus filed for the Registration Statement.

“Purchaser Party” shall have the meaning ascribed to such term in Section 4.8.

“Registration Statement” means the effective registration statement on Form S-1, (File No. 333-276562) filed with Commission and which registers the sale of the Units, Shares, Warrants, and Warrant Shares to the Purchasers, and includes any Rule 462(b) Registration Statement.

“Required Approvals” shall have the meaning ascribed to such term in Section 3.1(e).

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

“Rule 424” means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

“Rule 462(b) Registration Statement” means any registration statement prepared by the Company registering additional Securities, which was filed with the Commission on or prior to the date hereof and became automatically effective pursuant to Rule 462(b) promulgated by the Commission pursuant to the Securities Act.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(h).

“Securities” means the Units, Shares, Warrants and Warrant Shares.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Shares” means the shares of Common Stock issued or issuable to each Purchaser pursuant to this Agreement.

“Short Sales” means all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Common Stock).

“Subsidiary” means any subsidiary of the Company, which is actively engaged in a trade or business, and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Sullivan” means Sullivan & Worcester LLP, with offices located at 1633 Broadway, New York, New York 10019.

“Trading Day” means a day on which the principal Trading Market is open for trading.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transaction Documents” means this Agreement, the Warrants, the Lock-Up Agreement, the Placement Agency Agreement, the Warrant Agency Agreement, all exhibits and schedules thereto and hereto, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

“Transfer Agent” means Equiniti Trust Company, LLC, the current transfer agent of the Company, with a mailing address of 6201 15th Avenue, Brooklyn, NY, 11219, and any successor transfer agent of the Company.

“Units” means, collectively the Common Units and Pre-Funded Units.

“Unit Subscription Amount” means, as to each Purchaser, the aggregate amount to be paid for Units purchased hereunder as specified below such Purchaser’s name on the signature page of this Agreement and next to the heading “Unit Subscription Amount,” in United States dollars and in immediately available funds.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrants” means, collectively, the Common Warrants and Pre-Funded Warrants, if any.

“Warrant Agency Agreement” means that certain warrant agency agreement, dated as of [●], 2024, by and between the Company and the Transfer Agent, as warrant agent.

“Warrant Shares” means the shares of Common Stock issuable upon exercise of the Warrants.

ARTICLE II. PURCHASE AND SALE

2.1 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, up to an aggregate of \$[] of Common Units, determined pursuant to Section 2.2(a); provided, however, that, to the extent that a Purchaser determines, in its sole discretion, that such Purchaser (together with such Purchaser’s Affiliates, and any Person acting as a group together with such purchaser or any of such Purchaser’s Affiliates) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below), or as such Purchaser may otherwise choose, in lieu of purchasing Common Units such Purchaser may elect to purchase Pre-Funded Units at the Pre-Funded Unit Purchase Price in lieu of Common Units. The “Beneficial Ownership Limitation” shall be 4.99% (or, at the election of the Purchaser at Closing, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of the Securities on the Closing Date. Unless otherwise directed by the Placement Agents, each Purchaser’s Unit Subscription Amount as set forth on the signature page hereto executed by such Purchaser shall be made available for “Delivery Versus Payment” (“DVP”)/“Receipt Versus Payment” (“RVP”) settlement with the Company or its designee. The Company shall deliver to each Purchaser its respective Shares, Common Warrants and/or Pre-Funded Warrants (as applicable to such Purchaser), and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of Sullivan or such other location as the parties shall mutually agree or virtually in accordance with the provisions of this Agreement. Unless otherwise directed by the Placement Agents, settlement of the Shares shall occur via DVP/RVP (i.e., on the Closing Date, the Company shall issue the Shares registered in the Purchasers’ names and addresses and released by the Transfer Agent directly to the account(s) at the Placement Agents identified by each Purchaser; upon receipt of such Shares, the Placement Agents shall promptly electronically deliver such Shares to the applicable Purchaser, and payment therefor shall be made by the Placement Agents (or their clearing firm) by wire transfer to the Company), and delivery of the [Warrants]¹ shall be made via The Depository Trust Company Deposit or Withdrawal at Custodian system (“DWAC”) for the account of the applicable Purchaser. Notwithstanding anything herein to the contrary, if at any time on or after the time of execution of this Agreement by the Company and an applicable Purchaser, through, and including the time immediately prior to the Closing (the “Pre-Settlement Period”), such Purchaser sells to any Person all, or any portion, of the Shares to be issued hereunder to such Purchaser at the Closing (collectively, the “Pre-Settlement Shares”), such Purchaser shall, automatically hereunder (without any additional required actions by such Purchaser or the Company), be deemed to be unconditionally bound to purchase such Pre-Settlement Shares at the Closing; provided, that the Company shall not be required to deliver any Pre-Settlement Shares to such Purchaser prior to the Company’s receipt of the purchase price of such Pre-Settlement Shares hereunder; and provided further that the Company hereby acknowledges and agrees that the forgoing shall not constitute a representation or covenant by such Purchaser as to whether or not during the Pre-Settlement Period such Purchaser shall sell any shares of Common Stock to any Person and that any such decision to sell any shares of Common Stock by such Purchaser shall solely be made at the time such Purchaser elects to effect any such sale, if any. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise (as defined in the Pre-Funded Warrants) delivered on or prior to 12:00 p.m. (New York City time) on the Closing Date, which may be delivered at any time after the time of execution of this Agreement, the Company agrees to deliver the Pre-Funded Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Closing Date and the Closing Date shall be the Warrant Share Delivery Date (as defined in the Pre-Funded Warrants) for purposes hereunder.

¹ TBD if both Common Warrants and Pre-Funded Warrants will be settled via DWAC, or Common Warrants only.

2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company;

(ii) a legal opinion of Company Counsel, including without limitation, a negative assurance letter, in a form and substance reasonably satisfactory to the Placement Agents;

(iii) the Company shall have provided the Placement Agents and/or each Purchaser with the Company's wire instructions, on Company letterhead and executed by the Chief Executive Officer or Chief Financial Officer;

(iv) a copy of the irrevocable instructions to the Transfer Agent instructing the Transfer Agent to deliver on an expedited basis via DWAC Shares equal to such Purchaser's Common Unit Subscription Amount divided by the Common Unit Purchase Price, registered in the name of such Purchaser;

(v) Common Warrants registered in the name of such Purchaser to purchase up to a number of shares of Common Stock equal to 100% of such Purchaser's Shares and Pre-Funded Warrants, with an exercise price equal to \$[___], subject to adjustment therein;

(vi) for each Purchaser of Pre-Funded Warrants pursuant to Section 2.1, a Pre-Funded Warrant registered in the name of such Purchaser to purchase up to a number of shares of Common Stock equal to the portion of such Purchaser's Pre-Funded Unit Subscription Amount applicable to Pre-Funded Units divided by the Pre-Funded Unit Purchase Price, with an exercise price equal to \$0.0001, subject to adjustment therein;

(vii) the duly executed Warrant Agency Agreement;

(viii) on the date hereof, the duly executed Lock-Up Agreements; and

(ix) the Preliminary Prospectus and the Prospectus (which may be delivered in accordance with Rule 172 under the Securities Act).

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) such Purchaser's Unit Subscription Amount, which shall be made available for DVP/RVP settlement with the Company or its designee.

2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(ii) all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(b) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(iv) there shall have been no Material Adverse Effect with respect to the Company since the date hereof;

(v) the Registration Statement shall be effective on the date of this Agreement and at the Closing Date, no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been instituted or shall be pending or contemplated by the Commission and any request on the part of the Commission for additional information shall have been complied with to the reasonable satisfaction of the Placement Agents; and

(vi) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The hereby makes the following representations and warranties to each Purchaser:

(a) Subsidiaries. All of the direct and indirect Subsidiaries of the Company are set forth in the Registration Statement. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. Each of the Company and its Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents to which the Company is a party and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, liquidation, possessory liens, rights of set off, merger, consolidation, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the statutory limitation of the time within which proceedings may be brought or availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, provincial, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.4 of this Agreement, (ii) such as have been obtained or made under the Securities Act, (iii) the filing with the Commission of the Prospectus, (iv) application(s) to each applicable Trading Market for the listing of the Shares and Warrant Shares for trading thereon in the time and manner required thereby, (v) such filings as are required to be made under applicable state securities laws and (vi) such as those that, if not obtained, given or made, would not reasonably be expected to result in a Material Adverse Effect (collectively, the "Required Approvals").

(f) Issuance of the Securities; Registration.

(i) The Shares and Warrant Shares to be issued are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, to the extent applicable, will be duly and validly issued, fully paid and non-assessable, free and clear of all Liens imposed by the Company. The Warrants have been duly authorized and, when executed and delivered by the Company against payment therefor pursuant to the applicable Transaction Documents, will be valid and binding agreements of the Company enforceable against the Company in accordance with their terms. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement and the Warrants. All corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken.

(ii) The Company has prepared and filed the Registration Statement in conformity with the requirements of the Securities Act, which became effective on [___], 2024 (the "Effective Date"), including the Prospectus, and such amendments and supplements thereto as may have been required to the date of this Agreement. The Registration Statement is effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of the Preliminary Prospectus or the Prospectus has been issued by the Commission and no proceedings for that purpose have been instituted or, to the knowledge of the Company, are threatened by the Commission. The Company, if required by the rules and regulations of the Commission, shall file the Prospectus with the Commission pursuant to Rule 424(b). At the time the Registration Statement and any amendments thereto became effective, at the date of this Agreement and at the Closing Date, the Registration Statement and any amendments thereto conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading; and the Pricing Prospectus, the Prospectus and any amendments or supplements thereto, at the time the Pricing Prospectus, the Prospectus or any amendment or supplements thereto, as applicable, was issued and at the Closing Date, conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. All corporate action required to be taken for the authorization, issuance and sale of the Shares, Warrants, and Warrant Shares has been duly and validly taken. The Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement and the Prospectus.

(g) Capitalization. The capitalization of the Company is as disclosed in the SEC Reports as of the date hereof. The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to applicable employee equity plans, and except as disclosed or contemplated in the SEC Reports. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. The Securities will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. There are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person (other than the Purchasers). There are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or “phantom stock” plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities.

(h) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Pricing Prospectus and the Prospectus, being collectively referred to herein as the “SEC Reports”) on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company is not and has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. The agreements and documents described in the Registration Statement, the Pricing Prospectus, the Prospectus and the SEC Reports conform in all material respects to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Registration Statement, the Pricing Prospectus, the Prospectus or the SEC Reports or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Pricing Prospectus, the Prospectus or the SEC Reports, or (ii) is material to the Company’s business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company’s knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors’ rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefore may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the Company’s actual knowledge any other party is in default thereunder and, to the Company’s actual knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. To the Company’s actual knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing Applicable Law or order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses, including, without limitation, those relating to environmental laws and regulations. The other financial and statistical information included in the SEC Reports present fairly, in all material respects, the information included therein and have been prepared on a basis consistent with that of the financial statements that are included in the SEC Reports and the books and records of the respective entities presented therein.

(i) Material Changes, Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company equity plans and employee stock purchase plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement or as set forth in the SEC Reports, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.

(j) Litigation. There has not been and to the knowledge of the Company, there is not pending or contemplated, any action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action"). Neither the Company nor any Subsidiary, nor, to the Company's knowledge, any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty or which could result in a Material Adverse Effect. To the knowledge of the Company there has not been, and there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. There are no Actions required to be disclosed in the SEC Reports that have not been disclosed. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(k) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company or any of its Subsidiaries, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or any Subsidiary's employees is a member of a union that relates to such employee's relationship with the Company or any Subsidiary, and neither the Company nor any Subsidiary is a party to a collective bargaining agreement, and the Company believes that its relationships with its employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any Subsidiary to any liability with respect to any of the foregoing matters. Each of the Company and its Subsidiaries is in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(l) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(m) Environmental Laws. Each of the Company and the Subsidiaries (i) is in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) has received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) is in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply or receive could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(n) Regulatory Permits. (1) Each of the Company and the Subsidiaries possesses all certificates, licenses, authorizations, approvals, clearances, consents, registration and permits issued by the appropriate federal, state, local or foreign regulatory authorities including, without limitation, those administered by the U.S. Food and Drug Administration ("FDA") of the U.S. Department of Health and Human Services, the Federal Trade Commission (the "FTC"), or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA and the FTC, or reasonably necessary to conduct their respective businesses as described in the Registration Statement or the Prospectus, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect (each an "Authorization"), and neither the Company nor any Subsidiary has received any written notice of proceedings relating to the revocation or modification of any Authorization or the noncompliance with any ordinance, law, rule or regulation applicable to the Company. The disclosures in the Registration Statement, if concerning the effects of federal, state, local and all foreign regulation on the Company's business as currently contemplated, are correct in all material respects. The Company is and has been in material compliance with any term of any such Authorizations, except for any violations which would not reasonably be expected to have a Material Adverse Effect. The Company has not failed to file with the applicable regulatory authorities (including the FDA or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) any filing, declaration, listing, registration, report or submission that is required to be so filed for the Company's business operation as currently conducted. All such filings were in material compliance with applicable laws when filed and no deficiencies have been asserted in writing by any applicable regulatory authority (including, without limitation, the FDA or any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) with respect to any such filings, declarations, listings, registrations, reports or submissions.

(2) Each of the Company and the Subsidiaries: (i) is and at all times has been in substantial compliance with all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, advertising, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company, including but not limited to the U.S. Food, Drug and Cosmetic Act (the “FDCA”) (21 U.S.C. § 301 et seq.), the Federal Trade Commission Act (15 U.S.C. § 41-58) and the rules and regulations of the Consumer Product Safety Commission (“Applicable Laws”), except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; (ii) has not received any warning letter, untitled letter or other correspondence or notice from any other governmental authority alleging or asserting noncompliance with any Applicable Laws or any Authorizations; (iii) possesses all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (iv) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) has not received notice that any governmental authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations and has no knowledge that any such governmental authority is considering such action and the FDA has not sent any warning letters; imposed any fines, penalties or injunctions; or required or requested termination of any distribution of the Company’s products; requested or required any recalls or seizures of products; or withdrawals or suspensions of clearances or approvals, resulting in prohibitions on sales of our products; (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (vii) to the Company’s knowledge, has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company’s knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(3) Neither the Company or any Subsidiary is aware of any manufacturing site (whether Company-owned or that of a third-party manufacturer for the Company’s products) that performs manufacturing activity for the Company subject to a governmental authority (including the FDA) shutdown or import or export prohibition.

(4) The statements included in the SEC Reports, the Registration Statement and the Prospectus under the caption: “Government Regulations” are true and correct in all material respects; and to the Company’s knowledge, there are no health care laws which as of this date are material to the business of the Company which is not described in the Registration Statement or the Prospectus.

(o) Title to Assets. Each of the Company and the Subsidiaries has good and marketable title in fee simple to or has valid and marketable rights to lease or otherwise use all real property and all personal property owned by them that is material to the business of the Company and the Subsidiaries, free and clear of all Liens, except for (i) Liens incurred in connection with purchase money security interests and equipment financings, (ii) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries, and (iii) Liens for the payment of federal, provincial, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company or any Subsidiary, as applicable, is in compliance except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(p) Intellectual Property. Each of the Company and the Subsidiaries has, or has rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the “Intellectual Property Rights”). Neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the operations of their respective businesses violate or infringe upon the intellectual property rights of any Person, except as could not have or reasonably be expected to have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. Each of the Company and the Subsidiaries has taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) Insurance. Each of the Company and the Subsidiaries is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage in an amount sufficient to run the Company’s and any Subsidiary’s current business. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(r) Transactions With Affiliates and Employees. Except as set forth in the Registration Statement, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for (i) payment of salary, bonus or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any equity incentive plan of the Company.

(s) Sarbanes-Oxley; Internal Accounting Controls. Each of the Company and the Subsidiaries is in compliance in all material respects with any and all applicable requirements of the Sarbanes-Oxley Act of 2002, as amended, that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) that is effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including that: (i) transactions are executed in accordance with management’s general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset and liability accountability, (iii) access to assets or incurrence of liabilities is permitted only in accordance with management’s general or specific authorization, and (iv) the recorded accountability for assets and liabilities is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries maintain disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Commission, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive officer or officers and its principal financial officer or officers, as appropriate, to allow timely decisions regarding required disclosure. The Company has not received any notice or correspondence from any accountant, governmental entity or other Person relating to any potential material weakness in any part of the internal controls over financial reporting of the Company. The Company’s certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the “Evaluation Date”). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(t) Certain Fees. Except for fees payable by the Company to the Placement Agents, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(u) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(v) Registration Rights. Except as disclosed in the SEC Reports, no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. The Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(x) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Purchasers as a result of the Purchasers and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchasers' ownership of the Securities.

(y) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information which is not otherwise disclosed in the Prospectus. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made and when made, not misleading. The statistical and market-related data included in the Prospectus, if any, are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources. The Company has obtained all consents required for the inclusion of such statistical and market-related data in the Prospectus. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(z) No Integrated Offering. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act and (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. As of the date hereof there are no material outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the avoidance of doubt, such reorganization does not include the Company's mergers, acquisitions or other strategic transactions which are not for the primary purpose of avoiding bankruptcy. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of \$50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of \$50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(bb) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, each of the Company and its Subsidiaries (i) has made or filed or secured extensions for filing of, all applicable United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatsoever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(cc) Foreign Corrupt Practices. Neither the Company, any Subsidiary, nor to the knowledge of the Company, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA. Each of the Company and the Subsidiaries has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company or any Subsidiary to comply in all material respects with the FCPA.

(dd) Illegal or Unauthorized Payments; Political Contributions. Neither the Company, any Subsidiary nor any of the officers, directors, employees, agents or other representatives of the Company or any other business entity or enterprise with which the Company is or has been affiliated or associated, has, directly or indirectly, made or authorized any payment, contribution or gift of money, property, or services, whether or not in contravention of applicable law, (i) as a kickback or bribe to any Person or (ii) to any political organization, or the holder of or any aspirant to any elective or appointive public office except for personal political contributions not involving the direct or indirect use of funds of the Company or any Subsidiary.

(ee) Accountants. The Company's registered independent accounting firm is Baker Tilly US, LLP. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2023.

(ff) Acknowledgment Regarding Purchasers' Purchase of Securities. The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchasers' purchase of the Securities. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(gg) Acknowledgment Regarding Purchaser's Trading Activity. Anything in this Agreement or elsewhere herein to the contrary notwithstanding (except for Sections 3.2(f) and 4.13 hereof), it is understood and acknowledged by the Company that: (i) none of the Purchasers has been asked by the Company to agree, nor has any Purchaser agreed, to desist from purchasing or selling, long and/or short, securities of the Company, or "derivative" securities based on securities issued by the Company or to hold the Securities for any specified term; (ii) past or future open market or other transactions by any Purchaser, specifically including, without limitation, Short Sales or "derivative" transactions, before or after the closing of this or future private placement transactions, may negatively impact the market price of the Company's publicly-traded securities; (iii) any Purchaser, and counter-parties in "derivative" transactions to which any such Purchaser is a party, directly or indirectly, presently may have a "short" position in the Common Stock, and (iv) each Purchaser shall not be deemed to have any affiliation with or control over any arm's length counter-party in any "derivative" transaction. The Company further understands and acknowledges that (y) one or more Purchasers may engage in hedging activities at various times during the period that the Securities are outstanding, including, without limitation, during the periods that the value of the Warrant Shares deliverable with respect to Securities are being determined, and (z) such hedging activities (if any) could reduce the value of the existing stockholders' equity interests in the Company at and after the time that the hedging activities are being conducted. The Company acknowledges that such aforementioned hedging activities do not constitute a breach of any of the Transaction Documents.

(hh) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Placement Agents in connection with the placement of the Securities.

(ii) D&O Questionnaires. To the Company's knowledge, all information contained in the questionnaires most recently completed by each of the Company's directors and officers and beneficial owner of 5% or more of the Common Stock or Common Stock Equivalents is true and correct in all respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires become inaccurate and incorrect.

(jj) Cybersecurity. (x) There has been no security breach or other compromise of or relating to any of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "IT Systems and Data"), except as would not, individually or in the aggregate, have a Material Adverse Effect, and (y) (i) the Company and the Subsidiaries have not been notified of, and have no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to its IT Systems and Data; (ii) the Company and the Subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iv) the Company and the Subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices.

(kk) Compliance with Data Privacy Laws. Each of the Company and its Subsidiaries is, and at all prior times was, in compliance with all applicable state, federal, and international data privacy and security laws and regulations (collectively, the “Privacy Laws”), except where the failure to so comply could not reasonably be expected to result in a Material Adverse Effect. To ensure compliance with the Privacy Laws, each of the Company and its Subsidiaries has in place and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of personal data (the “Policies”). Each of the Company and its Subsidiaries has at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements, except for any disclosures, inaccuracies or violations that could not reasonably be expected to result in a Material Adverse Effect. The Company further certifies that: (i) neither the Company nor any Subsidiary has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has knowledge of any event or condition that could reasonably be expected to result in any such notice; (ii) neither the Company nor any Subsidiary is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) neither the Company nor any Subsidiary is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law, in each case except as could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(ll) Stock Option Plans or Equity Incentive Plans. Each stock option granted by the Company under the Company’s stock option plan or equity incentive plan was granted (i) in accordance with the terms of the Company’s stock option plan or equity incentive plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company’s stock option plan or equity incentive plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(mm) Office of Foreign Assets Control. Neither the Company, nor any Subsidiary, nor, to the Company’s knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department (“OFAC”).

(nn) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser’s request.

(oo) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the “BHCA”) and to regulation by the Board of Governors of the Federal Reserve System (the “Federal Reserve”). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(pp) Money Laundering. The operations of each of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the “Money Laundering Laws”), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(qq) Officers’ Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to the Purchasers shall be deemed a representation and warranty by the Company to the Purchasers as to the matters covered thereby.

(rr) Board of Directors. The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 (“SOX”) and the rules promulgated thereunder applicable to the Company and the rules of the Trading Market. At least one member of the Board of Directors qualifies as a “financial expert” as such term is defined under SOX and the rules promulgated thereunder and the rules of the Trading Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as “independent” as defined under the rules of the Trading Market.

(ss) Ineligible Issuer Status. At the time of filing the Registration Statement and at the date hereof, the Company was not and is not an “ineligible issuer,” as defined under Rule 405 under the Securities Act.

(tt) No Relationships with Customers and Suppliers. No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company or any of the Company’s affiliates, on the other hand, which is required to be described in the Registration Statement and the Prospectus or a document incorporated by reference therein and which is not so described.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) Organization; Authority. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors’ rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Understandings or Arrangements. Such Purchaser is acquiring such Securities as principal for his, her or its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Purchaser’s right to sell the Shares pursuant to a registration statement or otherwise in compliance with applicable federal and state securities laws).

(c) [Reserved].

(d) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) Access to Information. Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Such Purchaser acknowledges and agrees that none of the Placement Agents or any Affiliate of the Placement Agents has provided such Purchaser with any information or advice with respect to the Securities nor is such information or advice necessary or desired. None of the Placement Agents or any of their Affiliates have made or makes any representation as to the Company or the quality of the Securities and the Placement Agents and any of their Affiliates may have acquired non-public information with respect to the Company which such Purchaser agrees need not be provided to it. In connection with the issuance of the Securities to such Purchaser, none of the Placement Agents or any of their Affiliates has acted as a financial advisor or fiduciary to such Purchaser.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that the Registration Statement was initially publicly filed with the Commission. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby. Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Warrant Shares. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance or resale of the Warrant Shares or if the Warrant is exercised via cashless exercise, the Warrant Shares issued pursuant to any such exercise shall be issued free of all legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale or resale of the Warrant Shares, the Company shall immediately notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale or resale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any Purchaser to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws). The Company shall use best efforts to keep a registration statement (including the Registration Statement) registering the issuance or resale of the Warrant Shares effective during the term of the Warrants.

4.2 Furnishing of Information. Until the earlier of the time that (i) no Purchaser owns any Securities or (ii) the Warrants have expired, the Company covenants to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act even if the Company is not then subject to the reporting requirements of the Exchange Act.

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4 Securities Laws Disclosure; Publicity. The Company shall (a) by the Disclosure Time, issue a press release disclosing the material terms of the transactions contemplated hereby, and (b) file a Current Report on Form 8-K, including the Transaction Documents as exhibits thereto, with the Commission within the time required by the Exchange Act. From and after the issuance of such press release, the Company represents to the Purchasers that it shall have publicly disclosed all material, non-public information delivered to any of the Purchasers by the Company or any of its Subsidiaries, or any of their respective officers, directors, employees, Affiliates or agents, including, without limitation, the Placement Agents, in connection with the transactions contemplated by the Transaction Documents. In addition, effective upon the issuance of such press release, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees, Affiliates or agents, including without limitation, the Placement Agents, on the one hand, and any of the Purchasers or any of their Affiliates on the other hand, shall terminate and be of no further force or effect. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. The Company and each Purchaser shall consult with each other in issuing any other press releases with respect to the transactions contemplated hereby, and neither the Company nor any Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of any Purchaser, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of such Purchaser, except (a) as required by federal securities law in connection with the filing of final Transaction Documents with the Commission and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (b) and reasonably cooperate with such Purchaser regarding such disclosure.

4.5 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Purchaser is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchasers.

4.6 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser shall have consented in writing to the receipt of such information and agreed in writing with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. To the extent that the Company, any of its Subsidiaries, or any of its respective officers, directors, agents, employees or Affiliates delivers any material, non-public information to a Purchaser without such Purchaser's consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of its Subsidiaries, or any of their respective officers, directors, employees, Affiliates or agents, including, without limitation, the Placement Agents, or a duty to the Company, any of its Subsidiaries or any of their respective officers, directors, employees, Affiliates or agents including, without limitation, the Placement Agents, not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously with the delivery of such notice file such notice with the Commission pursuant to a Current Report on Form 8-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.7 Use of Proceeds. The Company shall use the net proceeds from the sale of the Securities hereunder as described in the "Use of Proceeds" section of the Registration Statement and Prospectus.

4.8 Indemnification of Purchasers. Subject to the provisions of this Section 4.8, the Company will indemnify and hold each Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of such Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is solely based upon a material breach of such Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings such Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by such Purchaser Party which is finally judicially determined to constitute fraud, gross negligence or willful misconduct). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.8 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred, *provided that*, in the event that it is judicially determined in a final judgment not subject to appeal by a court of competent jurisdiction that such Purchaser Party was not entitled to receive payments for legal and other expenses pursuant to this subparagraph, the Purchaser Party will promptly return all sums that had been advanced pursuant hereto. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.9 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Shares pursuant to this Agreement and Warrant Shares upon exercise of the Warrants.

4.10 Listing of Common Stock. The Company hereby agrees to use its reasonable best efforts to maintain the listing of the Common Stock on the Trading Market for at least two (2) years after the Closing Date.

4.11 Effectiveness. The Company will use its best efforts to cause the Registration Statement to remain effective with a current prospectus covering the issuance of the Warrant Shares upon exercise of the Warrants.

4.12 Equal Treatment of Purchasers. No consideration (including any modification of any Transaction Document) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of the Transaction Documents unless the same consideration is also offered to all of the parties to such Transaction Document. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser and is intended for the Company to treat the Purchasers as a class and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition or voting of Securities or otherwise.

4.13 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.4, such Purchaser will maintain the confidentiality of the existence and terms of this transaction and the information included in the Transaction Documents (other than as disclosed to its legal and other representatives subject to confidentiality obligations). Notwithstanding the foregoing, and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4, and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company or any of its Subsidiaries, or any of their respective officers, directors, employees, Affiliates or agents, including without limitation, the Placement Agents, after the issuance of the initial press release as described in Section 4.4. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement.

4.14 Exercise Procedures. The form of Notice of Exercise included in the Warrants set forth the totality of the procedures required of the Purchasers in order to exercise the Warrants. No additional legal opinion, other information or instructions shall be required of the Purchasers to exercise their Warrants. Without limiting the preceding sentences, no ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required in order to exercise the Warrants. The Company shall honor exercises of the Warrants and shall deliver Warrant Shares in accordance with the terms, conditions and time periods set forth in the Transaction Documents.

ARTICLE V. MISCELLANEOUS

5.1 Termination. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before the fifth (5th) Trading Day following the date hereof; provided, however, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, the Pricing Prospectus and the Prospectus, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via email attachment at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via email attachment at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers which purchased at least 50.1% in interest of the Shares and Pre-Funded Warrant Shares based on the initial Subscription Amounts hereunder (or, prior to the Closing, by the Company and each Purchaser) or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. Each of the Placement Agents shall be a third-party beneficiary of the representations and warranties of the Company in Section 3.1 and the representations and warranties of the Purchasers in Section 3.2. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.8 and this Section 5.8.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.8, the prevailing party in such Action or Proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities for a period of five (5) years from the Closing Date.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transaction Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docuSign.com), such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights; provided, however, that, in the case of a rescission of an exercise of a Warrant, the applicable Purchaser shall be required to return any shares of Common Stock subject to any such rescinded exercise notice concurrently with the return to such Purchaser of the aggregate exercise price paid to the Company for such shares and the restoration of such Purchaser's right to acquire such shares pursuant to such Purchaser's Warrant (including, if applicable, issuance of a replacement warrant certificate evidencing such restored right).

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. For reasons of administrative convenience only, each Purchaser and its respective counsel have chosen to communicate with the Company through Sullivan. Sullivan does not represent any of the Purchasers and only represents the Placement Agents. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers. Notwithstanding anything to the contrary in the foregoing, each of the Purchasers has been advised, and is being advised by this Agreement, to consult with an attorney before executing this Agreement, and each Purchaser has consulted (or had an opportunity to consult) with counsel of such Purchaser's choice concerning the terms and conditions of this Agreement and the other Transaction Documents for a reasonable period of time prior to the execution hereof and thereof.

5.18 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been canceled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement as set forth in the applicable Transaction Document.

5.21 WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

NUWELLIS, INC.

By: _____
Name: Nestor Jaramillo Jr
Title: President and Chief Executive Officer

Address for Notice:
12988 Valley View Road
Eden Prairie, MN 55344
Email: Nestor.Jaramillo@nuwellis.com

With a copy to (which shall not constitute notice):

Honigman LLP
650 Trade Centre Way, Suite 200
Kalamazoo, MI 49002
Attention: Phillip D. Torrence, Esq. or Jessica M. Herron, Esq.
Email: ptorrence@honigman.com or jherron@honigman.com

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK
SIGNATURE PAGE FOR PURCHASER FOLLOWS]

[Company Signature Page to Nuwellis, Inc. Securities Purchase Agreement]

[PURCHASER SIGNATURE PAGES TO NUWELLIS, INC.
SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: _____

Signature of Authorized Signatory of Purchaser: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Email Address of Authorized Signatory: _____

Address for Notice to Purchaser:

Address for Delivery of the Securities to Purchaser (if not same as address for notice):

DWAC for Shares: _____

Common Unit Subscription Amount: \$ _____

Common Units: _____

Pre-Funded Unit Subscription Amount: \$ _____

Pre-Funded Units: _____

Pre-Funded Warrant Shares: _____ Beneficial Ownership Blocker 4.99% or 9.99%

Common Warrant Shares: _____ Beneficial Ownership Blocker 4.99% or 9.99%

EIN Number: _____

Notwithstanding anything contained in this Agreement to the contrary, by checking this box (i) the obligations of the above-signed to purchase the securities set forth in this Agreement to be purchased from the Company by the above-signed, and the obligations of the Company to sell such securities to the above-signed, shall be unconditional and all conditions to Closing shall be disregarded, (ii) the Closing shall occur on the second (2nd) Trading Day following the date of this Agreement and (iii) any condition to Closing contemplated by this Agreement (but prior to being disregarded by clause (i) above) that required delivery by the Company or the above-signed of any agreement, instrument, certificate or the like or purchase price (as applicable) shall no longer be a condition and shall instead be an unconditional obligation of the Company or the above-signed (as applicable) to deliver such agreement, instrument, certificate or the like or purchase price (as applicable) to such other party on the Closing Date.

Exhibit A

Form of Common Warrant

Exhibit B

Form of Pre-Funded Warrant

Schedule A

Free Writing Prospectus

[None]²

² TBD

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation in the Registration Statement on Form S-1/A of Nuwellis, Inc. and Subsidiary of our report dated March 3, 2023, relating to the consolidated financial statements of Nuwellis, Inc. and subsidiary in the Annual Report on Form 10-K for the years ended December 31, 2022 and 2021, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
January 30, 2024

Calculation of Filing Fee Tables

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

Table 1: Newly Registered Securities

Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price(1)(2)	Fee Rate	Amount of Registration Fee(3)
Newly Registered Securities							
Equity	Units, consisting of:	Rule 457(g)	—	—	—	—	—
Equity	Shares of Common Stock, par value \$0.0001 per share	Rule 457(o)	—	—	\$8,000,000.00	\$0.00014760	\$1,180.80
Equity	Pre-Funded Warrants to purchase shares of Common Stock, par value \$0.0001 per share	Rule 457(g)	—	—	—	—	—
Equity	Shares of Common Stock, par value \$0.0001 per share, issuable upon exercise of the Pre-Funded Warrants	Rule 457(o)	—	—	Included above	—	—
Equity	Common Warrants to purchase shares of Common Stock, par value \$0.0001 per share	Rule 457(g)	—	—	—	—	—
Equity	Shares of Common Stock, par value \$0.0001 per share, issuable upon exercise of the Common Warrants	Rule 457(o)	—	—	\$8,000,000.00	\$0.00014760	\$1,180.80
Total Offering Amounts					\$16,000,000.00	\$0.00014760	\$2,361.60
Total Fees Previously Paid							\$738.00
Total Fee Offset							—
Net Fee Due							\$1,623.60

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), there are also being registered such indeterminate number of additional securities as may be issued to prevent dilution resulting from stock splits, stock dividends and similar transactions.
- (2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.
- (3) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum offering price.