As filed with the Securities and Exchange Commission on January 17, 2024
Registration No. 333-

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

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

Nuwellis, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**3845**	**68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(952) 345-4200
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Nestor Jaramillo, Jr.
Chief Executive Officer
Nuwellis, Inc.
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(952) 345-4200
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 17, 2024

PRELIMINARY PROSPECTUS

NUWELLIS, INC.

Up to [•] Units consisting of
[•] Shares of Common Stock and
[•] Common Warrants to purchase up to [•] Shares of Common Stock
Up to [•] Shares of Common Stock Underlying the Common Warrants included in the Units

Up to [•] Pre-Funded Units consisting of
[•] Pre-Funded Warrants to purchase up to [•] Shares of Common Stock and
[•] Common Warrants to purchase up to [•] Shares of Common Stock

Up to [•] Shares of Common Stock Underlying the Pre-Funded Warrants included in the Pre-Funded Units
Up to [•] 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 **[•]** 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 $**[•]** per unit, which is equal to the closing price of our common stock on the Nasdaq Capital Market on **[•]**, 2024 for gross proceeds of up to $**[•]**. The common warrants included in the units will have an exercise price of $**[•]** 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 **[•]**, 2024, the closing price of our common stock on the Nasdaq Capital Market was $**[•]** 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)."

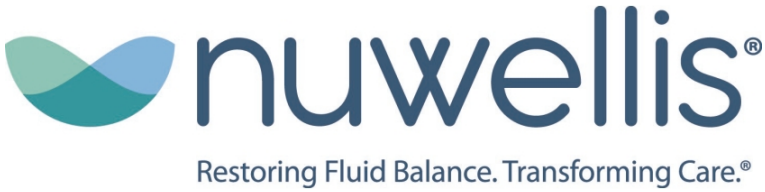
Delivery of the securities offered hereby is expected to be made on or about , 2024, subject to satisfaction of customary closing conditions.

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.

LAKE STREET **MAXIM GROUP LLC**

The date of this prospectus is _____, 2024



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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission ("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.

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[1]. The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight and edema), blood chemistry, electrocardiogram (ECG or EKG), glomerular filtration rate (GFR), liver enzymes, and urinalysis, or serum/urine sodium test. Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema[2] and is a leading cause of hospital readmissions with patients suffering from heart failure and patients following cardiac surgery.[3]

The condition of fluid overload is often observed in patients with heart failure and secondary oliguric states,[4] although in pediatric patients, fluid overload is associated with significant increases in mortality.[5, 6] Congestion or fluid overload, the hallmark of decompensated HF, is the primary reason for hospitalization in 90% of these patients.[6] For this reason, diuretics have been the cornerstone of heart failure treatment for more than 50 years.[7] Over the past 20 years, approaches to treatment have changed dramatically.[8] 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 fluid overload.[10, 11] These patients are hospitalized on average for 8.3

1 Vaara ST et al. Crit Care.2012; 16: 1-11.
2 Stein, A, et. al. Critical Care, 2012:16:R99.
3 Iribarne A, et al. Ann Thorac Surg. 2014; 98(4): 1274-80.
4 Ronco C, Costanzo MR, Bellomo R, et al. (2010) Fluid Overload Diagnosis and Management. Basel, Switzerland: Karger.
5 Sutherland SM, et al. Am J Kidney Disease. 2010; 5(2): 316-25.
6 Gillespie RS, et al. Ped Nephro. 2004; 19(12): 1394-99.
7 Kazory A & Costanzo MR. Extracorporeal isolated ultrafiltration for management of congestion in heart failure and cardiorenal syndrome. Adv Chronic Kidney Dis. 2018; 25(5): 434-442.
8 Kamath, SA. The role of ultrafiltration in patients with decompensated heart failure. Int J of Nephrol. 2011; 1-6.
9 Ellison DH. Diuretic therapy and resistance in congestive heart failure. Cardiology.2001;96:132-143
10 Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445.
11 McIlvennan CK, Eapen ZJ, Allen LA. Hospital readmissions reduction program. Circulation. 2015 May 19;131(20):1796-803.

days at a cost of approximately $24,000[12], to which reimbursement will only cover about 34%[13] of that cost. On top of that, there is a 30-day readmission rate in which the hospitals absorb another cost but do not get reimbursed. [14, 15]

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.[16] 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.[17, 18] Diuretic resistance is associated with a higher risk of in-hospital worsening of heart failure, increase mortality after discharge, and a 3-fold increase inn rehospitalization rates.[19] In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.[20] Also, long term use of diuretics has been associated with kidney damage.[21] Approximately 40% of heart failure patients have poor diuretic response.[22] 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.[23] 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 ≥ 2.27 kg. (5 lbs.), and 16% gained weight during hospitalization.[24]

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[25] 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.[26, 27] Regardless of diuretic strategy, 42% of acutely decompensated heart failure subjects

[12] From Premier Applied Sciences database.

[13] Reimbursement estimates from MCRA.

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

[15] McIlvennan CK, Eapen ZJ, Allen LA. Hospital readmissions reduction program. Circulation. 2015 May 19;131(20):1796-803.

[16] Ahmed A, et al. Heart failure, chronic diuretic use, and increase in mortality and hospitalization: an observational study using propensity score methods. Eur Heart J. 2006 Jun;27(12):1431-9.

[17] Kazory A & Costanzo MR. Extracorporeal isolated ultrafiltration for management of congestion in heart failure and cardiorenal syndrome. Adv Chronic Kidney Dis. 2018; 25(5): 434-442; 30.

[18] Testani JM, Hanberg JS, Cheng S et al. Rapid and highly accurate prediction of poor loop diuretic natriuretic response in patients with heart failure. Circ Heart Fail. 2016; 9(1): e002370.

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

[20] Kamath SA. The role of ultrafiltration in patients with decompensated heart failure. Int J of Nephrol. 2011.

[21] Felker MG. Diuretics and ultrafiltration in acute decompensated heart failure J Am Coll Cardiol 2012 Jun 12;59(24):2145-53.

[22] Testani JM, Hanberg JS, Cheng S, et al. Rapid and highly accurate prediction of poor loop diuretic natriuretic response in patients with heart failure. Circ Heart Fail. 2016 Jan;9(1):e002370.

[23] Hoorn EJ and Ellison DH. Diuretic Resistance. Am J Kidney Dis. 2017;69(1):136-142.

[24] Gheorghiade M, Filippatos G. Reassessing treatment of acute heart failure syndromes: the ADHERE registry. Eur Heart J Suppl. 2005; 7:B13–19.

[25] Orso D, Tavazzi G, Corradi F, et al. Comparison of diuretic strategies in diuretic-resistant acute heart failure: a systematic review and network meta-analysis. Eur Rev Med Pharmacol Sci. 2021 Apr;25(7):2971-2980.

[26] Costanzo MR, Ronco C, Abraham WT, et al, Extracorporeal Ultrafiltration for Fluid Overload in Heart Failure: Current Status and Prospects for Further Research. J Am Coll Cardiol. 2017 May 16;69(19):2428- 2445.

[27] Thandra A, Balakrishna AM, Walters RW et al. Trends in and predictors of multiple readmissions following heart failure hospitlaization: A National wide analysis from the United States. Clin Invest. 2023; 365(2): 145-51.

in the DOSE (Diuretic Optimization Strategies Evaluation) trial reached the composite endpoint of death, rehospitalization, or emergency department visit at 60 days.[28] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[29] Therefore, an alternative therapy to help stabilize or improve patient care is needed.

Ultrafiltration

Ultrafiltration, or aquapheresis, is an alternative therapy to diuretics for fluid removal in patients with volume overload. Ultrafiltration has been a well-documented technique in the treatment of fluid overload in heart failure patients for over 20 years.[30] 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.[31] 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.[32]

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.[33] Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex System may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies.

Benefits of the Aquadex System

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

- Reduces hospitalization by 81%[34] compared to diuretics;
- Rehospitalizations with Aquadex were 48% lower than the national average at 30 days;[35]
- Reduces length of hospital stay when initiated early, resulting in average savings of $3,975 (14%);[36]
- Stabilizes or improves cardiac hemodynamics;[37, 38]
- Safe, easy-to-use, and flexible in application;

[28] Felker GM, Lee KL, Bull DA, et al. Diuretic strategies in patients with acute decompensated heart failure. N Engl J Med. 2011; 364:797–805.

[29] Costanzo MR, Guglin ME, Saltzberg MT, et al. Ultrafiltration versus intravenous diuretics for patients hospitalized for acute decompensated heart failure. J Am Coll Cardiol. 2007; 49(6):675-683.

[30] Agostoni PG, Marenzi GC, Pepi M, et al. Isolated ultrafiltration in moderate congestive heart failure. J Am Coll Cardiol. 1993; 21(2):424-431.

[31] Kazory A, Sgarabotto, Ronco C. Extracorporeal ultrafiltration for acute heart failure. 2023;13(1)1-8.

[32] Costanza MR, et. al. Ultrafiltration vs. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Value Health. 2018; 21 (Suppl 1):S167.

[33] SAFE Trial: Jaski BE, et al. J Card Fail. 2003 Jun; 9(3): 227-231; RAPID Trial: Bart BA, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2043-2046.

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

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

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

[37] Boga M, Islamoglu M, Badak I et al. The effects of modified hemofiltration on inflammatory mediators and cardiac performance in coronary artery bypass grafting. Perf. 2000; ;15:143-150.

[38] Kiziltepe U, Uysalel A, Corapcioglu T. et al. Effects of Combined conventional and modified ultrafiltration in adult patients. Ann Thorac Surg 2001;71:684–93.

- 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);[39]
- No significant changes to kidney function;[40]
- The use of continuous hematocrit monitoring and SvO2 sensor provides guided-therapy ultrafiltration.[41]
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;[42]
- 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.[43] 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.[44] 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.[45] Annual hospitalizations for heart failure exceed one million in both the United States

[39] Kazory A, Sgarabotto, Ronco C. Extracorporeal ultrafiltration for acute heart failure. 2023;13(1)1-8.

[40] Kazory A, Sgarabotto, Ronco C. Extracorporeal ultrafiltration for acute heart failure. 2023;13(1)1-8.

[41] Starr MC, et al. Pediatric Nephrology, September 2023.

[42] Costanzo MR, Saltzberg M, O'Sullivan J. Early ultrafiltration in patients with decompensated heart failure and diuretic resistance. J Am Coll Cardiol. 2005; 46(11): 2047-51.

[43] Shah, K, Xu, H, Matsouaka, R. et al. Heart failure with preserved, borderline, and reduced ejection fraction: 5-Year Outcomes. J Am Coll Cardiol. 2017 Nov, 70 (20) 2476–2486.

[44] Bozhurt B, Ahmad T, Alexander K, et al. Heart failure epidemiology and outcomes statistics: a report of the Heart Failure Society of America. J Card Fail. 2023; 29(10): 1412-42.

[45] Benjamin EJ, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation. 2017;135:00-00. (e378).

and Europe, and more than 90% are due to symptoms and signs of fluid overload.[46] In addition, approximately 68% of patients are discharged with sub-optimal results.[47] 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 progressive disease caused by impairment of the left side 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.

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.[48] 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 78% of patients are admitted directly to the emergency department as the first point of care.[49]

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.[50] As the population ages, healthcare expenditures are expected to increase substantially.[51] 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.

The Company believes the total U.S. heart failure market is approximately $1 billion[52] 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)

[46] Fonarow GC. The acute decompensated heart failure national registry (ADHERE): Opportunities to improve care of patients hospitalized with acute decompensated heart failure. Rev Cardiovasc Med. 2003; 4: s21-30.

[47] Testani JM, Hanberg JS, Cheng S et al. Rapid and highly accurate prediction of poor loop diuretic natriuretic response in patients with heart failure. Circ Heart Fail. 2016; 9(1): e002370.

[48] ADHERE Scientific Advisory Committee. ADHERE Final Cumulative National Benchmark Report. Mountain View, CA: Scios Inc.; 2006.

[49] Costanzo MR, Ronco C, Abraham WT, et al, Extracorporeal Ultrafiltration for Fluid Overload in Heart Failure: Current Status and Prospects for Further Research. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445.

[50] Voigt J, John S, Taylor A, Krucoff M, Reynolds M, Gibson CM. A Reevaluation of the costs of heart failure and its implications for allocation of health resources in the United States. Clin Cardiol. 2014;37(5): 312–321.

[51] Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013;6(3):606-619.

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

procedures,[53] 180,000 valve procedures,[54] and 3,000 VAD implants.[55] Cardiac surgery is associated with a degree of fluid overload due to cardiopulmonary bypass. Cardiopulmonary bypass often requires a physician to administer a high volume of pre- and post-operative fluids (e.g., cardiopulmonary bypass pumps prime fluid, fluid used for cardioplegia, other fluids administered to address hypotension or post-operative crystalloid). Fluid overload in post-cardiac surgery can readily occur because surgery can affect the pumping actions of the heart, leading to postoperative hemodynamic instability. The condition often remains symptomless for several days until clinical symptoms become apparent, when treatment is almost always too late and ineffective.[56]

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. 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.[57] 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.[58] 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.[59] Positive research has been recently published demonstrating the value of ultrafiltration in high-risk coronary artery bypass grafting surgery.[60] 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.[61]

The Company believes the total U.S. critical care failure market is approximately $900 million[62] 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 failure[63] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation.[64, 65, 66] Fluid overload drives pediatric morbidity and mortality risk in critically ill patients. 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.[67, 68]

The Company believes that the total U.S. pediatric market for fluid overload is approximately $130 million[69] and that roughly 30% of its revenue is derived from the treatment of pediatric patients.

[53] https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/.

[54] https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/.

[55] Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.

[56] Xu J, Shen B, Fang Y, et al. Postoperative fluid overload is a useful predictor of the short-term outcome of renal replacement therapy for acute kidney injury after cardiac surgery. Medicine. 2015;94(33):e1360.

[57] Crawford TC, Magruder JT, Grimm JC, et al. Complications after cardiac surgery: All are not created equal. Ann Thorac Surg. 2017;103:32-40.

[58] Iribane A, Chang H, Alexander Jh, et al. Readmissions after cardiac surgery: Experience of the national institutes of health/Canadian institutes of health research cardiothoracic surgical trials network. Ann Thorac Surg. 2014;98:1274-80.

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

[60] Beckles DL et al. The use of simple ultrafiltration technology as a fluid management strategy for highrisk coronary artery bypass grafting surgery. J Card Surg.2022; 37: 2951-57.

[61] Engelman D, et al. Ann Thorac Surg 2023;115:11-5A

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

[63] Jayaprasad. Heart Views. 2016 Jul-Sep; 17(3): 92–99.

[64] https://www.cdc.gov/ncbddd/heartdefects/data.html.

[65] Karamlou T, et al. J Thorac Cardiovasc Surg. 2013 Feb;145(2):470-5. doi: 10.1016/j.jtcvs.2012.11.037. Epub 2012 Dec 14.

[66] https://www.organdonor.gov/about/donors/child-infant.html.

[67] Sutherland SM, et al. American Journal of Kidney Diseases, vol. 55, no. 2, pp. 316-325, February 2010, 2.

[68] Gillespie RS, et al. Pediatric Nephrology, vol. 19, no. 12, pp. 1394-1399, December 2004.

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

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.

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.

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,*"[70] 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.[71] Additionally, another 2022 peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients.[72] 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

[70] Watson R, Haas D, Hummel et al. Ten year real world experience with ultrafiltration for the management of acute decompensated heart failure. Am Heart J Plus: Cardiol Res & Pract 24. 2022; 1-6.

[71] Watson R, Haas D, Hummel et al. Ten year real world experience with ultrafiltration for the management of acute decompensated heart failure. Am Heart J Plus: Cardiol Res & Pract 24. 2022; 1-6.

[72] Jain A, Agarwal N, Kazory A. Heart Fail Rev.2016;21(5):611-9.

financial burden associated with the care of heart failure patients.[73] 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.[74]

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 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.[75]

One 2019 peer reviewed paper reported on a multicenter, retrospective case series of children who received kidney replacement therapy (KRT) with an ultrafiltration device.[76] Patients were grouped according to weight 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.[77]

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").

[73] Kazory A, Sgarabotto A, Ronco C. Extracorporeal ultrafiltration for acute heart failure. Cardio Renal Med. 2023.12(1):1-8.

[74] Costanzo MR, Fonarow GC, Rizzo JA. Ultrafiltration vs. diuretics for the treatment of fluid overload in heart failure patients: A hospital cost analysis. Val in Health. 2018: 21(1): s167.

[75] Costanzo MR, Negoianu D, Jaski BE, et al. Aquapheresis versus intravenous diuretics and hospitalizations for heart failure, JACC: Heart Failure.2016;4(2):95-105.

[76] Menon S, Broderick J, Munshi R, et al. Kidney Support in Children using an Ultrafiltration Device: A Multicenter, Retrospective Study. Clin J Am Soc Nephrol. 2019 ;14(10):1432-1440.

[77] Menon S, Broderick J, Munshi R, et al. Kidney Support in Children using an Ultrafiltration Device: A Multicenter, Retrospective Study. Clin J Am Soc Nephrol. 2019 ;14(10):1432-1440.

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.

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 [•] 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 $[•] per share (equal to 100% of the 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 [•] 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 $[•] per unit, which represents the closing price of our common stock on the Nasdaq Capital Market on [•], 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 $[•], after deducting the placement agent fees and estimated offering expenses payable by us. However, this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, and we may not sell all or any of these securities offered pursuant to this prospectus; as a result, we may receive significantly less in net proceeds. We intend to use the net proceeds of this offering for working capital and for

	general corporate purposes, including for continued investments in our commercialization efforts. For additional information please refer to the section entitled "Use of Proceeds" on page 37 of this prospectus.
Risk Factors	Investing in our securities involves a high degree of risk and purchasers of our securities may lose their entire investment. See the information under the captions "Summary of Risk Factors" and "Risk Factors" beginning on page 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.
Listing of Common Stock	Our common stock is listed on the Nasdaq Capital Market under the ticker symbol "NUWE". There is no established trading market for the common warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the common warrants or the pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the common warrants and the pre-funded warrants will be extremely limited.
Reasonable Best Efforts Offering	We have agreed to offer and sell the securities offered hereby to the purchasers through the placement 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 102 of this prospectus.
Conflicts of Interest	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)."

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:

- 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.

You will experience immediate dilution in the net tangible book value per share of the common stock you purchase, and may experience additional dilution in the future.

Because the effective price per share of common stock included in the units or issuable upon exercise of the warrants or pre-funded warrants being offered may be higher than the net tangible book value per share of our common stock, you may experience dilution to the extent of the difference between the effective offering price per share of common stock you pay in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering. Assuming the sale of [•] units at a public offering price of $[•] per unit and our as adjusted net tangible book value as of September 30, 2023, and assuming no sale of any pre-funded units in this offering, no exercise of any of the common warrants being offered in this offering, and after deducting the placement agent fees and estimated offering expenses payable by us, you will incur immediate dilution in as adjusted, pro forma net tangible book value of approximately $[•] per share. As a result of the dilution to investors purchasing securities in this offering, investors may receive less than the purchase price paid in this offering, if anything, in the event of the liquidation of our company. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you participate in this offering.

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

Our management will have broad discretion in the application of the net proceeds we receive in this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether our management is using the net proceeds appropriately. Because of the number and variability of factors that will determine our use of our net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a

material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest our net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

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

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

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

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

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 further 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.

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 $[•] per share (equal to 100% of the 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 $[•] per share of common stock (equal to 100% of the 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.

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 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. 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 favorable 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 (≥ 20kg). 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.

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, 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 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 futures 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-one 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 December 31, 2023, we owned 15 issued patents and 15 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 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 $**[•]** (assuming the sale of all units offered hereby at the assumed public offering price of $**[•]** per unit, which represents the closing sale price of our common stock on the Nasdaq Capital Market on **[•]**, 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 $**[•]** and $**[•]**, 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 $[•]. 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 $[•] and $[•], 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 $**[•]** per unit would increase or decrease the net proceeds from this offering by $**[•]**, 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 **[•]** 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 $**[•]**, assuming the assumed public offering price of $**[•]** 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.

DILUTION

If you purchase securities in this offering, your ownership interest will be diluted immediately to the extent of the difference between the assumed public offering price per unit and as adjusted, net tangible book value per share of common stock immediately after this offering. Tangible assets equal our total assets less goodwill and intangible assets. As of September 30, 2023, our historical net tangible book value was $7,839,000 or $4.21 per share of common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of September 30, 2023.

Pro forma net tangible book value per share represents the amount of our total tangible assets as adjusted to take into account net cash proceeds of approximately $1,482,000 from our public offering, which closed on October 17, 2023. After giving effect to this transaction, our pro forma net tangible book value per share as of September 30, 2023 would have been approximately $5.00 per share.

After giving effect to the sale by us in this offering of **[•]** units at an assumed public offering price of $**[•]** per unit (the closing sale price of our common stock on the Nasdaq Capital Market on **[•]**, 2024), assuming no sale of any pre-funded units in this offering and no exercise of any of the common warrants being offered in this offering and deducting the placement agent fees and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2023, would have been $**[•]**, or $**[•]** per share of common stock. This amount represents an immediate increase in net tangible book value of $**[•]** per share to our existing shareholders and an immediate dilution of $**[•]** per share to purchasers of our securities in this offering. We determine dilution per share to investors participating in this offering by subtracting the pro forma as adjusted net tangible book value per share after this offering from the offering price per share paid by investors participating in this offering.

The following table illustrates this per share dilution:

Assumed public offering price per unit		$**[•]**
Historical net tangible book value per share at September 30, 2023	$4.21	
Pro forma net tangible book value per share at September 30, 2023	$5.00	
Increase in pro forma as adjusted net tangible book value per share attributable to this offering		$**[•]**
Pro forma as adjusted net tangible book value per share after giving effect to this offering		$**[•]**
Dilution per share to investors purchasing securities in this offering		$**[•]**

If we only sell 75% or 50% of the maximum offering amount, our pro forma as adjusted net tangible book value per share after this offering would be $**[•]**, or $**[•]**, respectively, and the dilution per share to investors purchasing securities in this offering would be $**[•]** or **[•]**, respectively, assuming no pre-funded warrants are issued and no warrants are exercised, and after deducting placement agent fees and estimated offering expenses payable by us.

A $0.05 increase or decrease in the assumed public offering price of $**[•]** per unit would increase or decrease the net proceeds from this offering by $**[•]**, 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 **[•]** 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 $**[•]**, assuming the assumed public offering price of $**[•]** 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.

The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of units that we offer in this offering, and other terms of this offering determined at the time of pricing. The foregoing discussion and table assumes no sale of pre-funded units, which if sold, would reduce the number of units that we are offering on a one-for-one basis. In addition, we may choose to raise additional capital due to market conditions or strategic considerations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The number of shares of our common stock to be outstanding after this offering is based on 1,864,265 shares of our 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 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 common stock issuable upon the conversion of the 127 outstanding shares of our Series F Preferred Stock;
- 3,712,871 shares of 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.

To the extent that outstanding convertible preferred stock, options or warrants are converted or exercised, you could experience further dilution. In addition, 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. To the extent that additional capital is raised through the sale of additional equity, the issuance of these shares could result in further dilution to our stockholders.

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 $[•] per unit, which represents the closing sale price of our common stock on the Nasdaq Capital Market on [•], and an aggregate offering amount of $[•], 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	
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 [•] 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, 5,682,461 and [•] shares actual, pro forma and pro forma as adjusted, respectively	—	—	
Additional paid-in capital	289,980	291,462	
Accumulated other comprehensive income:			
Foreign currency translation adjustment	(24)	(24)	
Unrealized gain on marketable securities	—	—	
Accumulated deficit	(282,117)	(282,117)	
Total stockholders' equity	7,839	9,321	

A decrease in the number of units offered by us to [•] units (resulting in proceeds of approximately $[•]) would decrease cash, decrease stockholders' equity, and decrease total capitalization on a pro forma as adjusted basis by approximately $[•] from the amounts presented in the table above, assuming the assumed offering price of $[•] per unit remains the same, and after deducting placement agent fees and estimated offering expenses payable by us. A decrease in the number of units offered by us to [•] units (resulting in proceeds of approximately $[•]) would decrease cash, decrease total stockholders' equity, and decrease total capitalization on a pro forma as adjusted basis by approximately $[•] from the amounts presented in the table above, assuming the assumed offering price of $[•] 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.

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 $[•] 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.

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.

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

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 as an allowance its estimate of expected credit losses. The CECL model applies to most debt instruments, trade receivables, lease receivables, financial guarantee contracts, and other loan commitments. The CECL model does not have a minimum threshold for recognition of impairment losses, and entities will need to measure expected credit losses on assets that have a low risk of loss. As a smaller reporting company pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended, these changes became effective for the Company on January 1, 2023. The adoption of ASU 2016-13 did not have any impact on the Company's consolidated financial statements.

FINANCIAL OVERVIEW

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

clinical studies. During 2016, we acquired the Aquadex Business and announced that we were halting all clinical evaluations of our prior technology, the C-Pulse System. Since then, our activities have consisted mainly of expanding our sales and marketing capabilities, performing clinical research, and engaging in new product development. As of 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%

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:

(in thousands)	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 overallotment 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.

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.

BUSINESS

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.

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[78]. The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight and edema), blood chemistry, electrocardiogram (ECG or EKG), glomerular filtration rate (GFR), liver enzymes, and urinalysis, or serum/urine sodium test. Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema[79] and is a leading cause of hospital readmissions with patients suffering from heart failure and patients following cardiac surgery.[80]

The condition of fluid overload is often observed in patients with heart failure and secondary oliguric states,[81] although in pediatric patients, fluid overload is associated with significant increases in mortality.[82, 83] Congestion or fluid overload, the hallmark of decompensated HF, is the primary reason for hospitalization in 90% of these patients.[84] For this reason, diuretics have been the cornerstone of heart failure treatment for more than 50 years.[85] Over the past 20 years, approaches to treatment have changed dramatically.[86] 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 fluid overload.[87, 88] These patients are hospitalized on average for 8.3 days at a cost of approximately $24,000[89], to which reimbursement will only cover about 34%[90] of that cost. On top of that, there is a 30-DAY readmission rate in which the hospitals absorb another cost but do not get reimbursed.[91, 92]

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[83] Gillespie RS, et al. Ped Nephro. 2004; 19(12): 1394-99.

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

[88] McIlvennan CK, Eapen ZJ, Allen LA. Hospital readmissionsreduction program. Circulation. 2015 May 19;131(20):1796-803.

[89] From Premier Applied Sciences database.

[90] Reimbursement estimates from MCRA.

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

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.[93] 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.[94, 95] Diuretic resistance is associated with a higher risk of in-hospital worsening of heart failure, increase mortality after discharge, and a 3-fold increase inn rehospitalization rates.[96] In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.[97] Also, long term use of diuretics has been associated with kidney damage.[98] Approximately 40% of heart failure patients have poor diuretic response.[99] 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.[100] 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 ≥ 2.27 kg. (5 lbs.), and 16% gained weight during hospitalization.[101]

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[102] 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.[103, 104] 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.[105] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[106] Therefore, an alternative therapy to help stabilize or improve patient care is needed.

[92] McIlvennan CK, Eapen ZJ, Allen LA. Hospital readmissions reduction program. Circulation. 2015 May 19;131(20):1796-803.

[93] Ahmed A, et al. Heart failure, chronic diuretic use, and increase in mortality and hospitalization: an observational study using propensity score methods. Eur Heart J. 2006 Jun;27(12):1431-9.

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[99] Testani JM, Hanberg JS, Cheng S, et al. Rapid and highly accurate prediction of poor loop diuretic natriuretic response in patients with heart failure. Circ Heart Fail. 2016 Jan;9(1):e002370.

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[102] Orso D, Tavazzi G, Corradi F, et al. Comparison of diuretic strategies in diuretic-resistant acute heart failure: a systematic review and network meta-analysis. Eur Rev Med Pharmacol Sci. 2021 Apr;25(7):2971-2980.

[103] Costanzo MR, Ronco C, Abraham WT, et al, Extracorporeal Ultrafiltration for Fluid Overload in Heart Failure: Current Status and Prospects for Further Research. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445.

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[105] Felker GM, Lee KL, Bull DA, et al. Diuretic strategies in patients with acute decompensated heart failure. N Engl J Med. 2011; 364:797–805.

[106] Costanzo MR, Guglin ME, Saltzberg MT, et al. Ultrafiltration versus intravenous diuretics for patients hospitalized for acute decompensated heart failure. 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.[107] 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.[108] 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.[109]

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.[110, 111] Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex System may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies.

Benefits of the Aquadex System

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

- Reduces hospitalization by 81%[112] compared to diuretics;
- Rehospitalizations with Aquadex were 48% lower than the national average at 30 days;[113]
- Reduces length of hospital stay when initiated early, resulting in average savings of $3,975 (14%);[114]
- Stabilizes or improves cardiac hemodynamics;[115, 116]
- 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);[117]

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[113] Watson R et al. J Cardiac Fail. 2020; 26(10): s56.

[114] Kiziltepe, U, et al. Ann Thorac Surg. 2001;71(2): 684-93.

[115] Boga M, Islamoglu M, Badak I et al. The effects of modified hemofiltration on inflammatory mediators and cardiac performance in coronary artery bypass grafting. Perf. 2000; ;15:143-150.

[116] Kiziltepe U, Uysalel A, Corapcioglu T. et al. Effects of Combined conventional and modified ultrafiltration in adult patients. Ann Thorac Surg 2001;71:684–93.

[117] Kazory A, Sgarabotto, Ronco C. Extracorporeal ultrafiltration for acute heart failure. 2023;13(1)1-8.

- No significant changes to kidney function;[118]
- The use of continuous hematocrit monitoring and SvO2 sensor provides guided-therapy ultrafiltration.[119]
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;[120]
- 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.[121] 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.[122] 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.[123] 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.[124] In addition, approximately 68% of patients are discharged with sub-optimal results.[125] 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 progressive disease caused by impairment of the left side of the heart's ability to pump blood to the various organs of the body. Patients with heart failure and fluid overload commonly experience

[118] Kazory A, Sgarabotto, Ronco C. Extracorporeal ultrafiltration for acute heart failure. 2023;13(1)1-8.

[119] Starr MC, et al. Pediatric Nephrology, September 2023.

[120] Costanzo MR, Saltzberg M, O'Sullivan J. Early ultrafiltration in patients with decompensated heart failure and diuretic resistance. J Am Coll Cardiol. 2005; 46(11): 2047-51.

[121] Shah, K, Xu, H, Matsouaka, R. et al. Heart failure with preserved, borderline, and reduced ejection fraction: 5-Year Outcomes. J Am Coll Cardiol. 2017 Nov, 70 (20) 2476–2486.

[122] Bozhurt B, Ahmad T, Alexander K, et al. Heart failure epidemiology and outcomes statistics: a report of the Heart Failure Society of America. J Card Fail. 2023; 29(10): 1412-42.

[123] Benjamin EJ, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation. 2017;135:00-00. (e378).

[124] Fonarow GC. The acute decompensated heart failure national registry (ADHERE): Opportunities to improve care of patients hospitalized with acute decompensated heart failure. Rev Cardiovasc Med. 2003; 4: s21-30.

[125] Testani JM, Hanberg JS, Cheng S et al. Rapid and highly accurate prediction of poor loop diuretic natriuretic response in patients with heart failure. Circ Heart Fail. 2016; 9(1): e002370.

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.

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.[126] 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 78% of patients are admitted directly to the emergency department as the first point of care.[127]

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.[128] As the population ages, healthcare expenditures are expected to increase substantially.[129] 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.

The Company believes the total U.S. heart failure market is approximately $1 billion[130] 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,[131] 180,000 valve procedures,[132] and 3,000 VAD implants.[133] Cardiac surgery is associated with a degree of fluid overload due to cardiopulmonary bypass. Cardiopulmonary bypass often requires a physician to administer a high volume of pre- and post-operative fluids (e.g., cardiopulmonary bypass pumps prime fluid, fluid used for cardioplegia, other fluids administered to address hypotension or post-operative crystalloid). Fluid

[126] ADHERE Scientific Advisory Committee. ADHERE Final Cumulative National Benchmark Report. Mountain View, CA: Scios Inc.; 2006.

[127] Costanzo MR, Ronco C, Abraham WT, et al, Extracorporeal Ultrafiltration for Fluid Overload in Heart Failure: Current Status and Prospects for Further Research. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445.

[128] Voigt J, John S, Taylor A, Krucoff M, Reynolds M, Gibson CM. A Reevaluation of the costs of heart failure and its implications for allocation of health resources in the United States. Clin Cardiol. 2014;37(5): 312–321.

[129] Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013;6(3):606-619.

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

[131] https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/.

[132] https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/.

[133] Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.

overload in post-cardiac surgery can readily occur because surgery can affect the pumping actions of the heart, leading to postoperative hemodynamic instability. The condition often remains symptomless for several days until clinical symptoms become apparent, when treatment is almost always too late and ineffective.[134]

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. 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.[135] 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.[136] 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.[137] Positive research has been recently published demonstrating the value of ultrafiltration in high-risk coronary artery bypass grafting surgery.[138] 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.[139]

The Company believes the total U.S. critical care failure market is approximately $900 million[140] 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 failure[141] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation.[142,143,144] Fluid overload drives pediatric morbidity and mortality risk in critically ill patients. 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.[145, 146]

The Company believes that the total U.S. pediatric market for fluid overload is approximately $130 million[147] 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.

[134] Xu J, Shen B, Fang Y, et al. Postoperative fluid overload is a useful predictor of the short-term outcome of renal replacement therapy for acute kidney injury after cardiac surgery. Medicine. 2015;94(33):e1360. 2017;103:32-40.

[135] Crawford TC, Magruder JT, Grimm JC, et al. Complications after cardiac surgery: All are not created equal. Ann Thorac Surg. 2017;103:32-40.

[136] Iribane A, Chang H, Alexander Jh, et al. Readmissions after cardiac surgery: Experience of the national institutes of health/Canadian institutes of health research cardiothoracic surgical trials network. Ann Thorac Surg. 2014;98:1274-80.

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

[138] Beckles DL et al. The use of simple ultrafiltration technology as a fluid management strategy for highrisk coronary artery bypass grafting surgery. J Card Surg.2022; 37: 2951-57.

[139] Engelman D, et al. Ann Thorac Surg 2023;115:11-5A

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

[141] Jayaprasad. Heart Views. 2016 Jul-Sep; 17(3): 92–99.

[142] https://www.cdc.gov/ncbddd/heartdefects/data.html.

[143] Karamlou T, et al. J Thorac Cardiovasc Surg. 2013 Feb;145(2):470-5. doi: 10.1016/j.jtcvs.2012.11.037. Epub 2012 Dec 14.

[144] https://www.organdonor.gov/about/donors/child-infant.html.

[145] Sutherland SM, et al. American Journal of Kidney Diseases, vol. 55, no. 2, pp. 316-325, February 2010, 2.

[146] Gillespie RS, et al. Pediatric Nephrology, vol. 19, no. 12, pp. 1394-1399, December 2004.

[147] 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.

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,*"[148] 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.[149] Additionally, another 2022 peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients.[150] 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.[151] 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.[152]

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 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

[148] Watson R et al. J Cardiac Fail. 2020; 26(10): s56

[149] Watson R, Haas D, Hummel et al. Ten year real world experience with ultrafiltration for the management of acute decompensated heart failure. Am Heart J Plus: Cardiol Res & Pract 24. 2022; 1-6.

[150] Jain A, Agarwal N, Kazory A. Heart Fail Rev.2016;21(5):611-9.

[151] Kazory A, Sgarabotto L, Ronco C: Extracorporeal Ultrafiltration for Acute Heart Failure. Cardiorenal Med 2023;13:1-8.

[152] Costanzo MR, Fonarow GC, Rizzo JA. Ultrafiltration vs. diuretics for the treatment of fluid overload in heart failure patients: A hospital cost analysis. Val in Health. 2018: 21(1): s167.

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.[153]

One 2019 peer reviewed paper reported on a multicenter, retrospective case series of children who received kidney replacement therapy (KRT) with an ultrafiltration device.[154] Patients were grouped according to weight 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.[155]

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").

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.

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

[153] Costanzo MR, Fonarow GC, Rizzo JA. Ultrafiltration vs. diuretics for the treatment of fluid overload in heart failure patients: A hospital cost analysis. Val in Health. 2018: 21(1): s167.

[154] Menon S, Broderick J, Munshi R, et al. Kidney Support in Children using an Ultrafiltration Device: A Multicenter, Retrospective Study. Clin J Am Soc Nephrol. 2019 ;14(10):1432-1440.

[155] Menon S, Broderick J, Munshi R, et al. Kidney Support in Children using an Ultrafiltration Device: A Multicenter, Retrospective Study. Clin J Am Soc Nephrol. 2019 ;14(10):1432-1440.

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,[156] ECMO therapy,[157] solid organ transplantation,[158] 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 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

[156] Elliott MJ.Ann Thorac Surg 1993;56:1518-22. fluid overload

[157] Selewski DT, et al. Crit Care Med. 2012 September; 40(9): 2694-2699. doi:10.1097/CCM.0b013e318258ff01.

[158] Riley AA. BMC Nephrology. 2018; volume 19, Article number: 268

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.[159]

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.

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

[159] https://www.ncbi.nlm.nih.gov/pubmed/23833312

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.[160] 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.[161] 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.[162] 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.

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,"*[163] studied the effectiveness of ultrafiltration therapy compared to diuretics in 801 patients hospitalized with acute

[160] Urban S, Błaziak M, Biegus J, Zymliński R. Ultrafiltration in acute heart failure: Current knowledge and fields for further research. Adv Clin Exp Med. 2021;30(7):737-746. doi:10.17219/acem/135347

[161] Grodin JL, et al. Eur J of Heart Fail. 2018 Jul;20(7):1148-1156.

[162] Rao VS, et al. Circ Heart Fail. 2019 Jun;12 (6):e005552.

[163] Urban S, Błaziak M, Biegus J, Zymliński R. Ultrafiltration in acute heart failure: Current knowledge and fields for further research. Adv Clin Exp Med. 2021;30(7):737-746. doi:10.17219/acem/135347

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 in High-Risk Post-operative Coronary Artery Bypass Grafting Patients,"*[164] 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,"[165] utilizing 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, 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,"[166] 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 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 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.

[164] Beckles D. et al. J of Card Fail. 2022 Feb; (37): 2951-2957.

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

[166] Hass DC, et al. Amer Heart J Plus. 2022 Dec; 24 (100230)

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-one 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 December 31, 2023, 15 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.

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;
- 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 Européene, 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 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.

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.

- 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.

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

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; Clarient, 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

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	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.	0	0	0
Michael McCormick	25,664	0	25,664
David McDonald	0	0	0
Jon W. Salveson	53,750	5,859	59,609
Gregory D. Waller	63,000	5,859	68,859
Warren S. Watson	49,326	5,859	55,185
Total	320,699	23,436	344,135

(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.

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 and 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 $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

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.

	2022			2023		
	Target		Earned	Target		Earned
Name	% 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.

	Option Awards[1]			
Name	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,

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

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).

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.

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.

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,

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, the public offering price set forth on the cover page of the prospectus.

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 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 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, 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

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 depositary 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

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,

us or any agent of ours. DTC may discontinue providing its services as securities depositary 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 depositary, or it is unable to continue or ceases to be a clearing agency registered under the Exchange Act and a successor depositary 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 depositary may register the ownership of uncertificated shares, which ownership shall be evidenced by periodic statements issued by the depositary 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

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 will be 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 will 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.

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

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 66⅔% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 66⅔% super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of our Company due to the significant amount of authorized, but unissued shares of our common stock and preferred stock;
- providing that, subject to the rights of the holders of any series of preferred stock, the number of directors shall be fixed from time to time exclusively by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- providing that any vacancies on our board of directors under certain circumstances will be filled only by a majority of our board of directors then in office, even if less than a quorum, and not by the stockholders.

Delaware Law

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

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

the transaction commenced, excluding for purposes of determining the number of shares outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (i) persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to that date, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

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

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

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

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

Choice of Forum

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

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

Limitation on Liability of Directors and Indemnification

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

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

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

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

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

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

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

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

Registration Rights

DaVita Supply Agreement. Concurrent with the signing of the Supply Agreement and issuance of the DaVita Warrant June 19, 2023, the Company entered into a Registration Rights Agreement ("Registration Rights Agreement") with DaVita, whereby the Company agreed, subject to DaVita's delivery of the Ultrafiltration Services Approval, 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 $[•] per share (equal to 100% of the 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.

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, 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 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 $[•] (equal to the purchase price per unit, 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 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.

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.

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 [•] units, based on an assumed public offering price of $[•] per unit, which represents the closing price of our common stock on the Nasdaq Capital Marked on [•], 2024, for gross proceeds of up to approximately $[•] 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 $[•], 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 form 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,

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

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.

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
Index to Consolidated Financial Statements

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.

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	396	328
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	21	21
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	—	179
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	(267,417)	(252,892)
Total stockholders' equity	12,357	25,947
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	4,755	4,491
Operating expenses:		
Selling, general and administrative	17,584	19,039
Research and development	4,342	4,978
Total operating expenses	21,926	24,017
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	$(14,525)	$(19,554)
Basic and diluted loss per share	$ (83.55)	$(285.36)
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	(7)	(4)
Total comprehensive loss	$(14,452)	$(19,582)

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	2	—	1	—	—	1
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	221,078	—	—	—	—	—
Balance December 31, 2022	536,394	$—	$279,736	$ 38	$(267,417)	$ 12,357

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	1,278	(211)
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	(122)	(219)
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	(26)	(26)
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	$ 17,737	$ 8,742
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.

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:

(Dollars in thousands)	2022	2021
Finished Goods	$ 993	$1,527
Work in Process	204	276
Raw Materials	1,609	1,281
Inventory Reserves	(145)	(241)
Total	$2,661	$2,843

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).

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	705,302	74,580

The following table reconciles reported net loss with reported net loss per share for the years ended December 31:

(in thousands, except per share amounts)	2022	2021
Net loss	$(14,525)	$(19,545)
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	$ (83.55)	$(285.36)

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 as an allowance its estimate of expected credit losses. The CECL model applies to most debt instruments, trade receivables, lease receivables, financial guarantee contracts, and other loan commitments. The CECL model does not have a minimum threshold for recognition of impairment losses, and entities will need to measure expected credit losses on assets that have a low risk of loss. As a smaller reporting company pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended, these changes 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

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:

(in thousands)	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	253	245
Total	4,151	4,008
Accumulated Depreciation	(3,171)	(2,820)
	$ 980	$ 1,188

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

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,

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 overallotment option.

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

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

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

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

The offering was comprised of (1) 209,940 Class A Units, priced at a public offering price of $25 per Class A Unit, with each Class A Unit consisting of one share of common stock 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

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

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.

	2022		2021	
(Dollars in thousands)	Fair Value	Level 1	Fair Value	Level 1
Marketable securities	$569	$569	$15,463	$15,463

The fair value of the Company's common stock warrant liability related to the investor warrants issued in the October 2022 public offering, was calculated using a Monte Carlo valuation model and was classified as Level 3 in the fair value hierarchy.

The following is a roll-forward of the fair value of 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:

	Oct. 18, 2022	Dec. 31, 2022
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)	2022	2021
Domestic	$(14,551)	$(19,582)
Foreign	35	37
Loss before income taxes	$(14,516)	$(19,545)

The components of income tax expense consist of the following for the years ended December 31:

(in thousands)	2022	2021
Current:		
United States and state	$—	$—
Foreign, net	(9)	(9)
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax expense	$ (9)	$ (9)

Actual income tax expense differs from statutory federal income tax expense as follows for the years ended December 31:

(in thousands)	2022	2021
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	$ (9)	$ (9)

Deferred taxes consist of the following as of December 31:

(in thousands)	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	$ —	$ —

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	**$365**	**$342**

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	1,111
Less: Interest	(155)
Present value of lease liability	**$ 956**

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.

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:

(in thousands)	**December 31, 2021**		
Consolidated Balance Sheet	**As reported**	**Adjustment**	**As revised**
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

(in thousands)	**As reported**	**Adjustment**	**As revised**
Other income (expense)	(43)	24	(19)
Unrealized gains (losses) on marketable securities	—	(24)	(24)
	(43)	—	(43)

Consolidated Statement of Cash Flows

(in thousands)	As reported	Adjustment	As revised
Net realized and unrealized gains on marketable securities	—	13	13
Net cash provided in operations	—	13	13
Purchases of marketable securities	—	(18,850)	(18,850)
Proceeds from sales of marketable securities	—	3,350	3,350
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	1,381	1,259	3,595	3,424
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	4,545	5,179	17,632	16,061
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	(2)	(2)	(6)	(6)
Net loss	**$(3,370)**	**$(3,870)**	**$(14,700)**	**$(12,629)**
Basic and diluted loss per share	**$ (1.81)**	**$(36.72)**	**$ (10.21)**	**$(119.85)**
Weighted average shares outstanding – basic and diluted	1,864	105	1,439	105
Other comprehensive loss:				
Foreign currency translation adjustments	$ —	$ 2	$ (6)	$ 1
Total comprehensive loss	**$(3,370)**	**$(3,868)**	**$(14,706)**	**$(12,628)**

See notes to the condensed consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARY
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share amounts)

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2021	**105,376**	**$—**	**$278,874**	**$(35)**	**$(252,892)**	**$25,947**
Net loss	—	—	—	—	(4,473)	(4,473)
Unrealized foreign currency translation adjustment	—	—	—	(2)	—	(2)
Stock-based compensation, net	—	—	241	—	—	241
Balance March 31, 2022	**105,376**	**$—**	**$279,115**	**$(37)**	**$(257,365)**	**$21,713**
Net loss	—	—	—	—	(4,286)	(4,286)
Foreign currency translation adjustment	—	—	—	1	—	1
Stock-based compensation, net	—	—	236	—	—	236
Balance June 30, 2022	**105,376**	**$—**	**$279,351**	**$(36)**	**$(261,651)**	**$17,664**
Net loss	—	—	—	—	(3,870)	(3,870)
Foreign currency translation adjustment	—	—	—	2	—	2
Stock-based compensation, net	—	—	220	—	—	220
Balance September 30, 2022	**105,376**	**$—**	**$279,571**	**$(34)**	**$(265,521)**	**$14,016**

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2022	**536,394**	**$—**	**$279,736**	**$ 38**	**$(267,417)**	**$12,357**
Net loss	—	—	—	—	(6,485)	(6,485)
Unrealized foreign currency translation adjustment	—	—	—	(7)	—	(7)
Unrealized gain on marketable securities	—	—	—	6	—	6
Stock-based compensation, net	—	—	181	—	—	181
Issuance costs related to 2022 common stock offering	—	—	(11)	—	—	(11)
Conversion of preferred stock into common stock	10,493	—	—	—	—	—
Reclassification of warrants to equity	—	—	7,623	—	—	7,623
Conversion of warrants into common stock	660,045	—	—	—	—	—
Balance March 31, 2023	**1,206,932**	**$—**	**$287,529**	**$ 37**	**$(273,902)**	**$13,664**
Net loss	—	—	—	—	(4,845)	(4,845)
Unrealized foreign currency translation adjustment	—	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	(61)	—	(61)
Stock-based compensation, net	—	—	197	—	—	197
Issuance costs related to ATM offering	—	—	(98)	—	—	(98)
Issuance of common stock from ATM offering	657,333	—	2,217	—	—	2,217
Balance June 30, 2023	**1,864,265**	**$—**	**$289,845**	**$(24)**	**$(278,747)**	**$11,074**
Net loss	—	—	—	—	(3,370)	(3,370)
Unrealized foreign currency translation adjustment	—	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	—	—	—
Stock-based compensation, net	—	—	135	—	—	135
Issuance costs related to ATM offering	—	—	—	—	—	—
Issuance of common stock from ATM offering	—	—	—	—	—	—
Balance September 30, 2023	**1,864,265**	**$—**	**$289,980**	**$(24)**	**$(282,117)**	**$ 7,839**

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)	$(12,629)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	253	301
Stock-based compensation expense, net	513	697
Change in fair value of warrant liability	755	—
Net realized gain on marketable securities	(65)	—
Changes in operating assets and liabilities:		
Accounts receivable	(19)	(350)
Inventory, net	325	(113)
Other current assets	(551)	(40)
Other assets and liabilities	(16)	(142)
Accounts payable and accrued expenses	(1,678)	254
Net cash used in operating activities	**(15,183)**	**(12,022)**
Investing Activities:		
Proceeds from sale of marketable securities	578	—
Additions to intangible assets	(99)	—
Purchases of property and equipment	(185)	(103)
Net cash provided by (used in) investing activities	**294**	**(103)**
Financing Activities:		
Proceeds from ATM stock offerings, net	2,108	—
Payments on finance lease liability	(20)	(28)
Net cash provided by (used in) financing activities	**2,088**	**(28)**
Effect of exchange rate changes on cash	(6)	1
Net decrease in cash and cash equivalents	(12,807)	(12,152)
Cash and cash equivalents - beginning of period	17,737	24,205
Cash and cash equivalents - end of period	**$ 4,930**	**$ 12,053**
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

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:

(in thousands)	September 30, 2023	December 31, 2022
Finished Goods	$ 811	$ 993
Work in Process	170	204
Raw Materials	1,659	1,609
Inventory Reserves	(304)	(145)
Total	$2,336	$2,661

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	1,424,626	29,388

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	
(in thousands, except per share amounts)	2023	2022	2023	2022
Net loss	$(3,370)	$(3,870)	$(14,700)	$(12,629)
Weighted average shares outstanding	1,864	105	1,439	105
Basic and diluted loss per share	$ (1.81)	$(36.72)	$ (10.21)	$(119.85)

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.

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 overallotment 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 overallotment option.

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

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

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

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

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:

	Three months ended September 30		Nine months ended September 30	
(in thousands)	2023	2022	2023	2022
Selling, general and administrative expense	$133	$199	$484	$624
Research and development expense	2	21	29	73
Total stock-based compensation expense	**$135**	**$220**	**$513**	**$697**

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.

- 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.

	September 30, 2023		December 31, 2022	
(in thousands)	**Fair Value**	**Level 1**	**Fair Value**	**Level 1**
Marketable securities	$0	$0	$569	$569

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:

(in thousands)	
Balance at December 31, 2022	$ 6,868
Change in fair value	755
Balance at January 4, 2023 (revaluation date)	7,623
Warrants reclassified to equity	(7,623)
Balance at September 30, 2023	$ —

Note 6 — Income Taxes

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of its deferred tax assets. The Company has established a full valuation allowance for its U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying condensed consolidated financial statements.

As of 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.

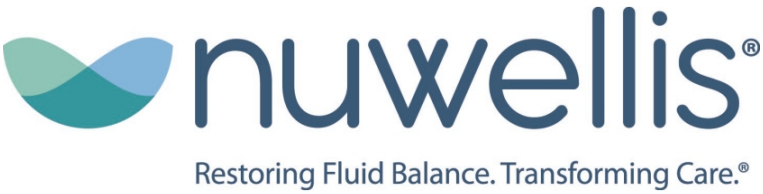
The October 2023 Warrants have a term of three (3) years. Each October 2023 Warrant has an exercise price of $7.50 (50.0% of the public offering price per Unit) per one-half of one share (0.5) of Series J Convertible Preferred Stock and is immediately exercisable.

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 [•] Units consisting of
[•] Shares of Common Stock and
[•] Common Warrants to purchase up to [•] Shares of Common Stock
Up to [•] Shares of Common Stock Underlying the Common Warrants included in the Units

Up to [•] Pre-Funded Units consisting of
[•] Pre-Funded Warrants to purchase up to [•] Shares of Common Stock and
[•] Common Warrants to purchase up to [•] Shares of Common Stock
Up to [•] Shares of Common Stock Underlying the Pre-Funded Warrants included in the Pre-Funded Units
Up to [•] 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*	$
FINRA Filing Fee*	$
Legal Fees and Expenses*	$
Accounting Fees and Expenses*	$
Miscellaneous Fees and Expenses*	$
Transfer Agent and Registrar Fees*	$
Total	$

* To be filed by amendment.

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.

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.

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				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
1.1	Form of Placement Agency* Agreement					
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
4.15	DaVita Inc. Common Stock Warrant Agreement+	8-K	001-35312	June 21, 2023	4.1	
4.16	Form of Common Warrant*					
4.17	Form of Pre-Funded Warrant*					
4.18	Form of Warrant Agency Agreement*					
5.1	Opinion of Honigman LLP*					
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.10	Fifth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	January 18, 2018	10.1	
10.11	Sixth Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2019	10.2	
10.12	Seventh Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	December 6, 2019	10.1	
10.13	Eighth Amendment to New-Hire Equity Incentive Plan†	8-K/A	001-35312	February 25, 2021	10.1	
10.14	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.2	
10.15	2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.1	
10.16	First Amendment to the 2017 Equity Incentive Plan†	14A	001-35312	September 11, 2020	App. A	
10.17	Second Amendment to the 2017 Equity Incentive Plan†	10-K	001-35312	March 3, 2023	10.17	
10.18	Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.2	
10.19	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.3	
10.20	Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.1	
10.21	First Amendment to the 2021 Inducement Plan†	8-K	001-35312	April 21, 2022	10.1	
10.22	Second Amendment to the 2021 Inducement Plan†	8-K	001-35312	March 1, 2023	10.1	
10.23	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.2	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.34	Warrant Agency Agreement, dated as of March 12, 2019, between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-35312	March 13, 2019	4.2	
10.35	Underwriting Agreement, dated as of March 8, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	March 13, 2019	1.1	
10.36	Form of Employee Proprietary Information, Inventions Assignment and Non-Competition Agreement for the Company's employees, including executive officers†	10-Q	001-35312	May, 9, 2019	10.3	
10.37	Offer Letter, by and between the Company and Nestor Jaramillo, dated April 12, 2019†	10-Q	001-35312	May 9, 2019	10.5	
10.38	Placement Agency Agreement, dated as of October 23, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	October 23, 2019	1.1	
10.39	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	
10.40	Placement Agency Agreement, dated as of November 4, 2019, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	November 4, 2019	1.1	
10.41	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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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 pagers 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 Thalman & Co. Inc.	8-K	0001-35312	August 21, 2020	1.1	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.70	Form of Securities Purchase Agreement*					
21.1	List of Subsidiaries	10-K	001-35312	March 3, 2023	21	
23.1	Consent of Honigman LLP*					
23.2	Consent of Baker Tilly US					X
24.1	Power of Attorney					X(included on signature page)
107	Filing Fee Table					X

* To be filed by amendment.

† 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

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 17th day of January, 2024.

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr.

Nestor Jaramillo, Jr.

Chief Executive Officer

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ John L. Erb John L. Erb	Chairman of the Board	January 17, 2024
/s/ Nestor Jaramillo, Jr. Nestor Jaramillo, Jr.	President, Chief Executive Officer and Director (principal executive officer)	January 17, 2024
/s/ Robert B. Scott Robert B. Scott	Chief Financial Officer (principal financial officer and principal accounting officer)	January 17, 2024
/s/ Maria Rosa Costanzo, M.D. Maria Rosa Costanzo, M.D.	Director	January 17, 2024
/s/ Michael McCormick Michael McCormick	Director	January 17, 2024
/s/ Archelle Georgiou, M.D. Archelle Georgiou, M.D.	Director	January 17, 2024
/s/ Gregory Waller Gregory Waller	Director	January 17, 2024
/s/ David McDonald David McDonald	Director	January 17, 2024

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation in the Registration Statement on Form S-1 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 17, 2024

Exhibit 107

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)	—	—	$2,500,000.00	$0.00014760	$369.00
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)	—	—	$2,500,000.00	$0.00014760	$369.00
			Total Offering Amounts		$5,000,000.00	$0.00014760	$738.00
			Total Fees Previously Paid				—
			Total Fee Offset				—
			Net Fee Due				$738.00

(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.