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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended: December 31, 2022

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from to

Commission file number 001-35312

NUWELLIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**68-0533453**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(Address of principal executive offices including zip code)

(952) 345-4200
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	NUWE	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Securities registered pursuant to Section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates of the registrant (based upon the June 30, 2022 closing sale price of $59.00 per share) was approximately $6.2 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of February 24, 2023 was 1,206,932 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2023 annual meeting of stockholders are incorporated by reference into Part III of this report to the extent described herein.

NUWELLIS, INC.
ANNUAL REPORT ON FORM 10-K
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the ***"Securities Act"***), and Section 21E of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***). These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in this Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the U.S. Securities and Exchange Commission (the ***"SEC"***) that advise interested parties of the risks and factors that may affect our business.

PART I

Item 1. 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. 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[1] and is a leading cause of hospital readmissions with patients suffering from heart failure and patients following cardiac surgery.

The condition of fluid overload is often observed in patients with heart failure and secondary oliguric states.[2] Most of the symptoms of congestive heart failure result from extracellular fluid volume. For this reason, diuretics have been the cornerstone of heart failure treatment for more than 50 years. Over the past 20 years, approaches to treatment have changed dramatically.[3] These dramatic improvements include new medications and new technologies, such as ultrafiltration, to help treat fluid overload.

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. Although diuretics are the mainstay of treatment for congestion or fluid overload, no randomized trials have shown the effects of diuretics on mortality in chronic heart failure patients. Furthermore, appropriate titration of diuretics, specifically in the heart failure population, is unclear. Increasing concern exists that diuretics, particularly at high doses, may be deleterious in the inpatient setting. In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.[4] Also, long term use of diuretics has been associated with kidney damage.[5] Approximately 40% of heart failure patients have poor diuretic response.[6] 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.[7] 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.[8]

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[1] Stein, Aet. al. Critical Care, 2012:16:R99
[2] Ronco C, Costanzo MR, Bellomo R, et al. (2010) Fluid Overload Diagnosis and Management. Basel, Switzerland: Karger.
[3] Ellison DH. Diuretic therapy and resistance in congestive heart failure. Cardiology.2001;96:132-143.
[4] Kamath SA. The role of ultrafiltration in patients with decompensated heart failure. Int J of Nephrol.2011.
[5] Felker MG. Diuretics and ultrafiltration in acute decompensated heart failure J Am Coll Cardiol 2012 Jun 12;59(24):2145-53.
[6] 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.
[7] Hoorn EJ and Ellison DH. Diuretic Resistance. Am J Kidney Dis. 2017;69(1):136-142.
[8] Costanzo MR, Ronco C, Abrahman WT, et al. Extracorporeal ultrafiltration for fluid overload in heart failure. J Am Coll Cardiol. 2017;69(19):2428-2445.

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[9] 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.[10] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[11] 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.[12] Ultrafiltration is a safe and effective alternative therapy to remove extra fluid and salt by gently filtering blood through an ultrafiltration system. 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.[13]

The Aquadex System

The Aquadex System is designed and clinically proven to simply, safely, and precisely remove excess fluid (primarily excess salt and water) from patients suffering from fluid overload who have failed diuretic therapy. 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.[14] Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex System may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies.

Benefits of the Aquadex System

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

- Provides 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;
- Removes isotonic fluid (extracts sodium while sparing potassium and magnesium);[15]
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;[16]
- 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;
- Has a built-in console that guides the medical practitioner through the setup and operational process;
- Decreased hospital readmissions and duration resulting in cost savings at 90 days[17][18]

[9] Gheorghiade M, Filippatos G. Reassessing treatment of acute heart failure syndromes: the ADHERE registry. Eur Heart J Suppl. 2005; 7:B13–19.
[10] 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.
[11] 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.
[12] Agostoni PG, Marenzi GC, Pepi M, et al. Isolated ultrafiltration in moderate congestive heart failure. J Am Coll Cardiol. 1993; 21(2):424-431.
[13] 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.
[14] 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.
[15] Ali SS, et al. Congest Heart Fail. 2009; 15(1):1-4.
[16] Marenzi G, et al. J Am Coll Cardiol. 2001 Oct; 38(4): 963-968.
[17] Costanzo MR, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2047-2051.
[18] Costanzo MR, et al. Ultrafiltration v. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Poster presented at the ISPOR meeting, May 23, 2018, Baltimore, MD, USA.

- Recent peer-reviewed clinical data favored adjustable Ultrafiltration using the Aquadex Systems over adjustable IV diuretics in reducing cardiovascular mortality and subsequent HF events when patients are unresponsive to diuretics treatment.[19]

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.

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

Our Market Opportunity

The Aquadex System is indicated for the treatment of patients suffering from fluid overload who have failed 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: critical care, heart failure and pediatrics.

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,[20] 180,000 valve procedures,[21] and 3,000 VAD implants.[22] 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.[23]

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.[24] 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.[25] 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.[26] Positive research has been recently published demonstrating the value of ultrafiltration in high-risk coronary artery bypass grafting surgery.[27] 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, or hospital protocol, proposed by the ERAS Society consensus guidelines.[28]

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[19] Pinney S, et al. Heart Failure Society of America Meeting; October 2022; Washington, DC.
[20] https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/.
[21] https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/.
[22] Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.
[23] 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.
[24] Crawford TC, Magruder JT, Grimm JC, et al. Complications after cardiac surgery: All are not created equal. Ann Thorac Surg. 2017;103:32-40.
[25] 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.
[26] Iribarne A, et al. Ann Thorac Surg. 2014 Oct; 98(4): 1274-80.
[27] Beckles D. et al. J of Card Fail. 2022 Feb; (37): 2951-2957
[28] Engelman D, et al. Ann Thorac Surg 2023;115:11-5A

Heart Failure

Heart failure is one of the leading causes 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. Based on data from the National Health and Nutrition Examination Survey conducted by the Centers for Disease Control and Prevention/National Center for Health Statistics from 2011 to 2014, the American Heart Association estimates that 6.5 million people in the United States, age 20 and over, had heart failure.[29] 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.[30] 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.[31] In addition, approximately 68% of patients are discharged with sub-optimal results.[32] 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 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.[33] This clinical evidence from the ADHERE registry clearly 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 22% and 6-month readmissions of 44%, while 78% of patients are admitted directly to the emergency department as the first point of care.[34,35]

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.[36] As the population ages, healthcare expenditures are expected to increase substantially.[37] 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.

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[29] 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).
[30] 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).
[31] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69(19): 2428-45.
[32] Testani JM, et al. Circ Heart Failure. 2016;9(1).
[33] ADHERE Scientific Advisory Committee. ADHERE Final Cumulative National Benchmark Report. Mountain View, CA: Scios Inc.; 2006.
[34] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69(19): 2428-2445.
[35] Krumholtz HM et. al. Arch Intern Med. 1997 Jan 13;157(1): 99-104—Ross JS, et al. Circ Heart Fail. 2010 Jan; 3(1): 97-103.
[36] 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.
[37] 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.

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 [38] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation. [39,40,41]

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,[42] ECMO therapy,[43] solid organ transplantation,[44] 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 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.

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[38] Jayaprasad. Heart Views. 2016 Jul-Sep; 17(3): 92–99.
[39] https://www.cdc.gov/ncbddd/heartdefects/data.html.
[40] 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.
[41] https://www.organdonor.gov/about/donors/child-infant.html.
[42] Elliott MJ.Ann Thorac Surg 1993;56:1518-22. fluid overload
[43] Selewski DT, et al. Crit Care Med. 2012 September; 40(9): 2694–2699. doi:10.1097/CCM.0b013e318258ff01.
[44] Riley AA. BMC Nephrology. 2018; volume 19, Article number: 268

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.[45]

Sales and Marketing

As of February 24, 2023, we had 35 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

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.[46] 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.[47] 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.[48] 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.

[45] https://www.ncbi.nlm.nih.gov/pubmed/23833312
[46] 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
[47] Grodin JL, et al. Eur J of Heart Fail. 2018 Jul;20(7):1148-1156.
[48] Rao VS, et al. Circ Heart Fail. 2019 Jun;12 (6):e005552.

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,"*[46] studied the effectiveness of ultrafiltration therapy compared to diuretics in 801 patients hospitalized with acute decompensated heart failure. The meta-analysis demonstrated ultrafiltration increases fluid removal and weight loss and reduces rehospitalization and the risk of worsening heart failure in congestive patients, suggesting ultrafiltration is a safe and effective treatment option for volume-overloaded heart failure patients.

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

In February 2022, a third party retrospectively reviewed and concluded, *"The Use of Ultrafiltration in High-Risk Post-operative Coronary Artery Bypass Grafting Patients,"*[49] 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 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,"*[50] 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,*"[51] 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.

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[49] Beckles D. et al. J of Card Fail. 2022 Feb; (37): 2951-2957.
[50] Pinney S, et al. Heart Failure Society of America Meeting; October 2022; Washington, DC.
[51] Hass DC, et al. Amer Heart J Plus. 2022 Dec; 24 (100230)

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 expect to initiate qualification activities in 2023. We are also evaluating diagnostic tools for physicians to use during an Aquadex therapy to more precisely determine the amount of excess fluid to be removed, the rate of ultrafiltration, and when to stop therapy as dry weight is approached.

Manufacturers and Suppliers

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

Intellectual Property

We have submitted patent applications to establish an intellectual property portfolio through which we seek to protect our system and technology. In connection with our acquisition of the Aquadex Business, we entered into a patent license agreement with Baxter pursuant to which we obtained, for no additional consideration, a worldwide license to 49 exclusively licensed and 9 non-exclusively licensed patents used in connection with the Aquadex System to make, have made, use, sell, offer for sale and import the Aquadex System in the "field of use." Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven "required maintenance patents," and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. We estimate that the patents licensed from Baxter will expire between approximately 2023 and 2026.

We have fifteen 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 February 28, 2023, 24 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 or for the AcQtrac Cardiovascular Monitoring System. We estimate that most of our currently issued U.S. patents will expire by 2025. 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—Risks Relating to our Intellectual Property."

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 31st, 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 26th, 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 26th, 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.

Employees

As of February 24, 2023, we had 70 full-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

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 ("Nasdaq") on February 16, 2012.

Our principal executive offices are located at 12988 Valley View Road, Eden Prairie, Minnesota 55344, and our telephone number is (952) 345-4200. Our website address is www.nuwellis.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q 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 Annual Report on Form 10-K.

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.

Item 1A. Risk Factors.

Our business faces many risks. We believe the risks described below are the material risks we face. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, together with the "Cautionary Note Regarding Forward-Looking Statements" and the other information contained in this Annual Report on Form 10-K and the other documents that we will file from time to time with the SEC.

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 $14.5 million and $19.6 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, our accumulated deficit was $267.4 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.

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 50.4% and 51.4% of our revenues in the years ended December 31, 2022 and 2021, respectively, with our largest customer representing 12.5% and 12.3%, 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.

During 2020 and 2021, we faced challenging social and economic conditions caused by the outbreak of the novel strain of coronavirus, SARS-CoV-2, and the resulting COVID-19 pandemic. The rapidly evolving COVID-19 pandemic disrupted our operations and forced us to implement changes to keep our customers, their patients, and our employees safe. These changes included restrictions on hospital access imposed on our field employees by customers working on the front lines of COVID-19 and managing the spread of the virus, changes to employee work practices by requiring employees to work remotely, and increased protocols to ensure the safety of those employees that remained on site. The ongoing impact of the COVID-19 pandemic on our operational and financial performance will depend on certain future developments, including the extent and duration of future outbreaks, the ongoing impact on our customers and hospital access restrictions imposed on our field employees, and effect on our vendors, all of which remain uncertain and cannot be predicted.

We may experience curtailed customer demand or constrained supply that could materially adversely impact our business, results of operations and overall financial performance in future periods. Specifically, we may again experience negative impacts from changes in how we conduct business due to the COVID-19 pandemic, including but not limited to restrictions on travel and in-person meetings, production delays, warehouses and staffing disruptions and shortages, decreases or delays in customer demand and spending, and difficulties or changes to our sales process and customer support.

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. In addition, the disruption created by COVID-19 created significant uncertainty about our ability to access the capital markets in future periods. As of the filing date of this Annual Report on Form 10-K, 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.

We have been negatively impacted by the prioritization of COVID-19 patients in hospitals.

As a result of the rise in COVID-19 cases due to the Omicron variant, in 2022 hospitals were prioritizing and allocating beds and other resources for COVID-19 patients. In this regard, emergencies for patients with heart failure, unrelated to COVID-19, decreased and there was less emergency usage of the Aquadex System. The impact of the Omicron variant resulted in a decrease in revenues for the fourth fiscal quarter of 2021 and had continuing effects into early 2022.

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 adopted in April 2017. The MDR replaces the existing Medical Device Directives (MDD 93/42/EEC and MDD 90/385/EEC). The new MDR went into effect on May 26, 2021, and new CE Mark product must comply with new MDR after this date. As of May 26,2021, companies that have devices on the market with CE Mark under MDD 93/42/EEC or MDD 90/385/EEC must meet the transitional provisions of the new MDR. Devices lawfully placed on the market under MDD 93/42/EEC or MDD 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.

By May 27, 2025, all medical devices entering the EU will need to have a new CE Mark under the MDR, even if they have been on the market previously under the MDD/AIMDD. Manufacturers are required to update their technical documentation and processes to meet the new requirements. Nuwellis™ received the CE Mark for Aquadex SmartFlow® on January 13, 2020. Nuwellis received the renewal certificate to include the 24-Hour blood circuit September 3rd, 2021. Our CE certificate for Aquadex SmartFlow® is under MDD/93/42 EEC and is valid through May 26,2024 which allow us to sell Aquadex SmartFlow® System into EU and satisfy future distribution demand.

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.

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 between approximately 2023 and 2026.

We have thirteen 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 February 24, 2023, we owned 38 issued patents and one pending patent applications in the United States and 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 2027. 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:

- halt use of our Aquadex System;
- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or
- 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 access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption 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.

Risks Related to Our Common Stock

Our failure to meet the continued listing requirements of the NASDAQ Capital Market could result in a delisting of our common stock.

Our common stock is listed on the Nasdaq Capital Market under the symbol "NUWE". In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, the minimum stockholders' equity requirement and the minimum bid price requirement. There can be no assurances that we will be successful in maintaining, or if we fall out of compliance, in regaining compliance with the continued listing requirements and maintaining the listing of our common stock on the Nasdaq Capital Market. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities and we would incur additional costs under requirements of state "blue sky" laws in connection with any sales of our securities. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. If our common stock is delisted by Nasdaq, the price of our common stock may decline and our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, which would negatively affect the liquidity of our common stock and an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock.

In addition, if our common stock is delisted from the Nasdaq Capital Market and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than $5.00 per share, subject to certain exceptions).

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 continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter.

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 February 24, 2023, we have warrants to purchase 19,190 shares of common stock outstanding, with exercise prices ranging from $25 to $89,040 with a weighted-average exercise price of $2,201.79.

As of February 24, 2023, there were 127 shares of Series F Preferred Stock outstanding, convertible into 5,080 shares of common stock. The certificate of designation for our Series F Preferred Stock contains an anti-dilution provision, which provision requires the lowering of the applicable conversion price, as then in effect, to the purchase price per share of common stock or common stock equivalents issued in the future. If the effective price per share on a common-stock equivalent basis in a future equity offering is lower than the then-current conversion price of the Series F Convertible Preferred Stock, then such conversion price shall be reduced to such lower price and additional shares of common stock will be issuable upon the conversion of the of the Series F Convertible Preferred Stock. To the extent the outstanding shares of Series F Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will experience further dilution.

If any security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock could depress the trading market for our common stock over an extended period of time. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2022, we have outstanding warrants to purchase an aggregate of approximately 679,244 shares of our common stock, and options to purchase an aggregate of approximately 10,485 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 as of February 24, 2023. Upon liquidation, dissolution or winding-up of the Company, holders of our Series F Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of such preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, pari passu with all the holders of common stock.

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

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 February 24, 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, 127 of which are designated Series F Preferred Stock, and we have 1,206,932 shares of common stock outstanding, 47,080 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, and 153,712 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. 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 $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.

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.

Item 3. Legal Proceedings.

We are not currently subject to any legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information. Commencing February 16, 2012, our shares of common stock began trading on Nasdaq, where it now trades under the symbol "NUWE." See "Risk Factors—Risks Related to Our Common Stock—Nasdaq may delist our common stock from its exchange which could limit your ability to make transactions in our securities and subject us to additional trading restrictions" under Part I, Item 1A of this Annual Report on Form 10-K.

Stockholders of Record. As of February 24, 2023, we had 1,206,932 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.

ITEM 6. [Reserved].

Not applicable.

ITEM 7. 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 together with our audited consolidated financial statements and related notes which are included elsewhere in this Annual Report on Form 10-K. Our actual results could differ materially from those anticipated in the forward-looking statements included in this discussion as a result of certain factors, including, but not limited to, those discussed in "Risk Factors" included elsewhere in this Annual Report on Form 10-K.

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 System. The Aquadex SmartFlow system is indicated for temporary (up to eight hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20kg or more whose fluid overload is unresponsive to medical management, including diuretics.

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 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 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 the years ended December 31, 2021 and 2020, 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 in the front lines of COVID-19 and managing the spread of the virus, changes to employees work practices by requiring employees to work remotely 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 will depend on certain future developments, including any future spread and duration of an outbreak, the ongoing impact on our customers and hospital access restrictions imposed on our field employees, and effect on our vendors, all of which remain uncertain and cannot be predicted.

We may experience curtailed customer demand or constrained supply that could materially adversely impact our business, results of operations and overall financial performance in future periods. Specifically, we may experience negative impacts from changes in how we conduct business due to the COVID-19 pandemic, including but not limited to restrictions on travel and in-person meetings, production delays, warehouses and staffing disruptions and shortages, decreases or delays in customer demand and spending, difficulties or changes to our sales process and customer support.

Several hospitals in the U.S. initially included the Aquadex System into their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff were limited, but treatment regimens subsequently evolved so that the need to restore fluid balance became less prevalent. However, we also experienced changes to our sales practices due to restrictions on hospital access and believe that revenue in other areas was negatively impacted by these restrictions. In addition, the disruption created by COVID-19 created significant uncertainty about our ability to access the capital markets in future periods. As of the filing date of this Form 10-K, the extent to which COVID-19 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. See Part 1, Item 1-A "Risk Factors" in this Annual Report on Form 10-K.

Recent Developments

Public Offerings

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 at a $0.00 exercise price.

On December 8, 2022, following a special meeting of stockholders held on December 5, the Board 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 is fixed and did not contain any variable pricing feature or any price-based anti-dilutive feature. The preferred stock issued in this transaction included a beneficial ownership blocker but had 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 became exercisable on January 4, 2023, following the effective date of a reverse stock split in an amount sufficient to permit the exercise in full of the warrants and upon stockholder approval of such reverse stock split and of the exercisability of the warrants under Nasdaq rules. The warrants will expire on the sixth anniversary of the initial exercise date.

Subsequent Events

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.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We have adopted various accounting policies to prepare the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). Our most significant accounting policies are disclosed in Note 1 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

The preparation of the consolidated financial statements, in conformity with U.S. GAAP, requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to stock-based compensation, valuation of equity instruments, inventory and accounts receivable reserves, potential impairment of long-lived assets 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.

Revenue Recognition
We recognize revenue in accordance with Accounting Standards Codification (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 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Accounts Receivable
Our accounts receivable generally have terms that require payment in 30 days. We did not establish an allowance for doubtful accounts on December 31, 2022, as we have not experienced any bad debt write-offs or a deterioration in the aging of our receivables to date and do not expect to experience in the future.

Inventories
Inventories represent primarily finished goods, raw materials and sub-assemblies 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 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.

Accounting for Warrants
We have issued and may continue to issue warrants to purchase shares of common stock through our public and private offerings. 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 balance sheet date.

The fair value of the warrant liability is estimated using a Monte Carlo simulation model using relevant inputs and assumptions based upon the terms of the warrants.

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 offerings. (See Note 4 – Stockholders' Equity to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.)

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 therefore bypassed, and the Company proceeded to measure fair value of the asset group. The Company has determined the fair value of the asset group using expected cash flows associated with its loaner units by 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 years ended December 31, 2022 or December 31, 2021.

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, 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 December 31, 2022, we had an accumulated deficit of $267.4 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, 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 expanding our sales and marketing capabilities, purchasing inventory and manufacturing components, investing in clinical research, 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 2021 and through December 31, 2022, we closed on underwritten public and other equity offerings for aggregate net proceeds of approximately $37.3 million after deducting the underwriting discounts and commissions or placement agents' fees and offering expenses, as applicable, and other costs associated with the offerings. See Note 4 –Stockholders' Equity, to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. 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 December 31, 2023; however, there can be no assurance of this. We may 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.

Internal Controls and Procedures

Our independent registered public accounting firm is not yet required to formally attest to the effectiveness of our internal control over financial reporting and will not be required to do so for as long as our public float remains below $75 million as of the last business day of our most recently completed second fiscal quarter. However, management is subject to Section 404(a) of the Sarbanes-Oxley Act of 2002 and is required to report annually on effectiveness of our internal control over financial reporting.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 2016, the FASB issued 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 the new standard will have a material impact on the Company's consolidated financial statements.

Information regarding new accounting pronouncements, when applicable, is included in Note 1 to the consolidated financial statements included in this Annual Report on Form 10-K. There are no new accounting pronouncements not yet adopted that we believe will have a material impact on the consolidated financial statements of the Company.

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 product development, and conducting preclinical 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 efforts, as well as continued development of clinical evidence and new product development efforts. As of December 31, 2022, we had an accumulated deficit of $267.4 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 successfully fund our operations in the future, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Net Sales
(dollars in thousands)

Year Ended December 31, 2022	Year Ended December 31, 2021	Increase (Decrease)	% Change
$ 8,543	$ 7,921	$ 622	7.9%

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 the United States to independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. Sales during the twelve months ended December 31, 2022, increased from console sales to both new and existing customers, higher circuit sales, and higher service-related revenue.

Costs and Expenses
Our costs and expenses were as follows:

(dollars in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021	Increase (Decrease)	% Change
Cost of goods sold	$ 3,788	$ 3,430	$ 358	10.4 %
Selling, general and administrative	$ 17,584	$ 19,039	$ (1,455)	(7.6%)
Research and development	$ 4,342	$ 4,978	$ (636)	(12.8%)

Cost of Goods Sold
The increase in costs of goods sold for the year ended December 31, 2022 compared to the year ended December 31, 2021, was due to higher sales, lower fixed overhead absorption because of lower manufacturing volumes, and a $97,000 inventory write-off resulting from the discontinuation of a distribution agreement.

Selling, General and Administrative
The decrease in selling, general and administrative expense primarily reflects the Company's ongoing expense reduction efforts. Selling, general and administrative expenses were also lower due to unfilled positions and non-recurring expenses in the prior year period.

Research and Development
The decrease in Research and Development (R&D) expenses over the prior year was primarily driven by expense of $428,160 in 2021 for a non-refundable technology license fee, as discussed in Note 10 – Commitments and Contingencies.

Income Tax Expense

(dollars in thousands)	Year Ended December 31, 2022	Year Ended December 31, 2021	Increase (Decrease)	% Change
Income tax expense	$ 9	$ 9	$ —	0.0%

We have not recognized any income tax benefit in our statement of operations related to our U.S. operating losses, as all tax benefits are fully reserved. We generate minimal amounts of income tax expense in connection with activities incurred by our Irish subsidiary.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through cash on hand and a series of equity and debt issuances. 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 February 24, 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,127 of which are designated Series F Preferred Stock, and 1,049,280 of which represent Series I preferred stock outstanding, and we have 1,206,932 shares of common stock outstanding, 47,080 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, and 153,712 shares of common stock reserved for future grant under the Company's equity incentive plans. All common stock share amounts reflected herein have been adjusted to give effect to the December 2022 reverse stock split.

On January 28, 2020, we closed on an underwritten public offering of 2,015 shares of common stock, 3,839 shares of Series H Preferred Stock and warrants to purchase 5,855 shares of common stock, which included the full exercise of the underwriter's over-allotment option, for gross proceeds of approximately $9.7 million. Net proceeds totaled approximately $8.6 million after deducting the underwriting discounts and commissions and other costs associated with the offering. See Note 4 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

On March 23, 2020, we closed on a registered direct offering of 1,387 shares of common stock for gross proceeds of approximately $1.2 million, prior to deduction of commissions and offering expenses related to the transaction. In a concurrent private placement, we 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. See Note 4 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

On April 1, 2020, we closed on a registered direct offering of 1,710 shares of common stock for gross proceeds of approximately $2.2 million, prior to deduction of commissions and offering expenses payable related to the transaction. In a concurrent private placement, we 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 were exercisable immediately and expire five and a half years from the date of issuance. See Note 4 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

On May 5, 2020, we closed on a registered direct offering of 1,199 shares of common stock 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, we 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 were exercisable immediately and will expire five and a half years from the date of issuance. See Note 4 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

On August 21, 2020, we closed on an underwritten public offering of 10,647 shares of common stock and warrants to purchase 10,647 shares of common stock, which included the full exercise of the underwriter's over-allotment option, for gross proceeds of approximately $14.4 million. Net proceeds totaled approximately $13.0 million after deducting the underwriting discounts and commissions and other costs associated with the offering. See Note 4 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

On March 19, 2021, we closed on an underwritten public offering of 37,958 shares of common stock, which included the full exercise of the underwriter's over-allotment option, for gross proceeds of approximately $20.9 million. 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. See Note 4 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

On September 17, 2021, we closed on an underwritten public offering of 40,056 shares of common stock, for gross proceeds of approximately $10.0 million. 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. See Note 4 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

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 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 that was held on December 5, 2022, 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 included 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 $165, based on "reset" provisions in the related warrant agreement.

As of December 31, 2022 and 2021, cash, cash equivalents, and marketable securites were $18.3 million and $24.2 million, respectively. Our business strategy and ability to fund our operations in the future depends 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 likely need to seek additional financing in the future, which, to date, has been through offerings of our equity.

Cash Flows from Operating Activities

Net cash used in operating activities was $15.1 million and $17.8 million in 2022 and 2021, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by stock-based compensation, depreciation and amortization, and the effects of changes in operating assets and liabilities, including working capital, as well as the net impact of non-cash financing expense and change in the fair value of the warrant liability for the current year period.

Cash Flows from Investing Activities

Net cash provided and (used) in investing activities was $14.7 million and ($15.7) million in 2022 and 2021, respectively. The cash provided in investing activities represented the proceeds from the sale of marketable securities and cash used in investing activities was primarily for the purchase of marketable securities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $9.4 million and $27.9 million in 2022 and 2021, respectively. The cash provided from financing activities in both years was the result of proceeds received from the Company's underwritten public offerings of equity securities.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2022, which represent material expected or contractually committed future obligations:

(Dollars in thousands)	Payments Due by Period				
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Operating Lease	$ 249	$ 521	$ 341	$ -	$ 1,111
Financing Leases	32	-	-	-	32
Total	$ 281	$ 521	$ 341	$ -	$ 1,343

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 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. The Company also entered into two finance leases in 2020 for computer hardware and audio-visual equipment with monthly payments of approximately $2,400 due through August 2023.

Capital Resource Requirements

As of December 31, 2022, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm (PCAOB ID 23)

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.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (together, the ***"Certifying Officers"***), as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired objectives. Also, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As of December 31, 2022, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2022.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and Board; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our management, including our Certifying Officers, recognizes that our internal control over financial reporting cannot prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management, with the participation of the Certifying Officers, assessed our internal control over financial reporting as of December 31, 2022, the end of our fiscal year. Management based its assessment on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2022.

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter ended December 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

"At the Market" Offering

On March 3, 2023, the Company entered into a Sales Agreement (the "Sales Agreement") with Ladenburg Thalmann & Co. Inc. ("Ladenburg") pursuant to which the Company may sell from time to time, at its option, up to an aggregate of $10.0 million of shares of its common stock through or to Ladenburg, as sales agent or principal. Sales of the Company's Common Stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Capital Market under the Company's Registration Statement on Form S-3 (File No. 333-256797), in sales deemed to be "at the market offerings" as defined in Rule 415 promulgated under the Securities Act. Ladenburg will use its commercially reasonable efforts to sell the Common Stock from time to time, based upon the Company's instructions (including any price, time, or size limits or other customary parameters or conditions the Company may impose).

The Company is not obligated to make any sales of Common Stock under the Sales Agreement, and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. The offering of Common Stock pursuant to the Sales Agreement will terminate upon the earlier of (i) sale of all of the shares of Common Stock subject to the Sales Agreement or (ii) termination of the Sales Agreement as permitted therein. The Company is obligated to pay Ladenburg an aggregate sales agent commission of up to 3.0% of the gross proceeds of the sale price for Common Stock sold under the Sales Agreement. The Company has also provided Ladenburg with customary indemnification rights and expense reimbursements for up to $70,000 of expenses in addition to ongoing diligence expenses.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed herewith as Exhibit 1.1 to this Current Report on Form 10-K.

The opinion of Honigman LLP relating to the shares of Common Stock being offered is filed as Exhibit 5.1 to this Current Report on Form 10-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is set forth under the following captions in our proxy statement to be filed with respect to the 2022 annual meeting of stockholders (the ***"Proxy Statement"***), all of which is incorporated herein by reference: "Proposal 1 — Election of Directors," "Board Matters — Board Committees," "Board Matters — Corporate Governance," "Executive Officers," and "Additional Matters — Delinquent Section 16(a) Reports."

Item 11. Executive Compensation.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: "Board Matters — Director Compensation," and "Named Executive Officer Compensation Tables."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: "Security Ownership of Certain Beneficial Owners and Management" and "Additional Matters — Equity Compensation Plan Information."

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: "Proposal 1 — Election of Directors — Director Independence" and "Certain Relationships and Related Person Transactions."

Item 14. Principal Accounting Fees and Services.

The information required by this item is set forth under the following captions in the Proxy Statement, all of which is incorporated herein by reference: "Audit Committee Matters."

PART IV

Item 15. Exhibits, and Financial Statement Schedules.

The following documents are filed as a part of this Annual Report on Form 10-K:

(a) Financial Statements: The financial statements filed as part of this report are listed in Part II, Item 8.

(b) Financial Statement Schedules: The schedules are either not applicable or the required information is presented in the consolidated financial statements or notes thereto.

(c) Exhibits: The following exhibits are incorporated by reference or filed as part of this Annual Report on Form 10-K:

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
1.1*	At The Market Offering Agreement, dated as of March 3, 2023, by and between the Company and Ladenburg Thalmann & Co. Inc.					X
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 Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	May 23, 2017	3.1	
3.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	October 12, 2017	3.1	
3.5	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1	
3.6	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K/A	001-35312	October 16, 2020	3.1	
3.7	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001.-35312	April 27, 2021	3.1	
3.8	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	December 9, 2022	3.1	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
3.9	Second Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2	
3.10	Amendment to Second Amended and Restated Bylaws	8-K	001-35312	October 5, 2022	3.1	
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	001-35312	November 17, 2017	3.7	
3.13	Certificate of Designation of Preferences, Rights and Limitations of Series I Convertible Preferred Stock	8-K	001-35312	October 18, 2022	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	

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

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
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*	Description of Securities					X
5.1*	Opinion of Honigman LLP					X
10.1	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	10.1	
10.2	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A	
10.3	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	May 29, 2013	10.2	
10.4	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2015	10.11	
10.5	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1	
10.6	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1	
10.7	Second Amendment to New-Hire Equity Incentive Plan†	S-8	333-202904	March 20, 2015	99.12	
10.8	Third Amendment to New-Hire Equity Incentive Plan†	S-8	333-210215	March 15, 2016	99.13	
10.9	Fourth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.4	

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

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.22	Second Amendment to the 2021 Inducement Plan †	8-K	001-35312	March 1, 2023	10.1	
10.23	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.2	
10.24	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1	
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) †					X
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	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
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	001-35312	November 23, 2021	10.1	
10.32	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1	
10.33	Letter Agreement dated February 15, 2017 among the Company, Sabby Volatility Warrant Master Fund, Ltd. and Sabby Healthcare Master Fund, Ltd.	8-K	003-35312	February 16, 2017	10.1	
10.34	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	
10.35	Form of Warrant Reprice Agreement	8-K	001-35312	June 29, 2018	10.1	
10.36	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	
10.37	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	
10.38	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	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.39	Offer Letter, by and between the Company and Nestor Jaramillo, dated April 12, 2019†	10-Q	001-35312	May 9, 2019	10.5	
10.40	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	
10.41	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	
10.42	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	
10.43	Form of Securities Purchase Agreement, dated as of November 4, 2019, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	November 4, 2019	10.1	
10.44	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	
10.45	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	
10.46	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	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.47	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	
10.48	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	
10.49	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	
10.50	Form of Securities Purchase Agreement, dated as of May 1, 2020, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	May 4, 2020	10.1	
10.51	Underwriting Agreement, dated as of August 19, 2020, by and between the Company and Ladenburg Thalman & Co. Inc.	8-K	001-35312	August 21, 2020	1.1	
10.52	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	
10.53	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	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.54	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	
10.55	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	
10.56	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	
10.57	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	
10.60	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	
10.61	First Amendment to Offer Letter between the Company and Lynn Blake†	8-K	001-35312	December 9, 2022	10.1	
10.62	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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.63*	License and Distribution Agreement with SeaStar Medical Holding Corporation, dated as of December 27, 2022+					X
21*	List of Subsidiaries					X
23.1*	Consent of Baker Tilly US, LLP					X
23.2*	Consent of Honigman LLP (included in Exhibit 5.1)					X
24	Power of Attorney (included on signature page)					X
31.1	Section 302 Certification—CEO					X
31.2	Section 302 Certification—CFO					X
32.1	Section 906 Certification—CEO					X
32.2	Section 906 Certification — CFO					X
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					X

† Indicates management compensatory plan, contract or arrangement.

+ Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request. Certain portions of the License and Distribution Agreement have been redacted pursuant to Item 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. A copy of the unredacted License and Distribution Agreement will be furnished to the SEC upon request.

* Furnished herewith. This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary

Not Applicable

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 3, 2023

NUWELLIS, INC.

By: /S/ NESTOR JARAMILLO JR
Nestor Jaramillo Jr
President and Chief Executive Officer

POWER OF ATTORNEY

Each individual person whose signature appears below hereby appoints Nestor Jaramillo and George Montague as attorneys-in-fact with full power of substitution, severally, to execute in the name and on behalf of each such person, individually and in each capacity stated below, one or more amendments to this annual report which amendments may make such changes in the report as the attorney-in-fact acting in the premises deems appropriate, to file any such amendment to the report with the SEC, and to take all other actions either of them deem necessary or advisable to enable the Company to comply with the rules, regulations and requirements of the SEC.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ NESTOR JARAMILLO JR Nestor Jaramillo Jr	President, Chief Executive Officer and Director (principal executive officer)	March 3, 2023
/S/ LYNN BLAKE Lynn Blake	Chief Financial Officer (principal financial and accounting officer)	March 3, 2023
/S/ JOHN L. ERB John L. Erb	Chairman of the Board and Director	March 3, 2023
/S/ MARIA ROSA COSTANZO Maria Rosa Costanzo	Director	March 3, 2023
/S/ JON W. SALVESON Jon W. Salveson	Director	March 3, 2023
/S/ GREGORY D. WALLER Gregory D. Waller	Director	March 3, 2023
/S/ WARREN S. WATSON Warren S. Watson	Director	March 3, 2023

Exhibit 1.1

AT THE MARKET OFFERING AGREEMENT

March 3, 2023

Ladenburg Thalmann & Co. Inc.
640 Fifth Avenue, 4th Floor
New York, NY 10019

Ladies and Gentlemen:

Nuwellis, Inc., a corporation organized under the laws of Delaware (the "Company"), confirms its agreement (this "Agreement") with Ladenburg Thalmann & Co. Inc. (the "Manager") as follows:

1. Definitions. The terms that follow, when used in this Agreement and any Terms Agreement, shall have the meanings indicated.

"Accountants" shall have the meaning ascribed to such term in Section 4(m).

"Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Action" shall have the meaning ascribed to such term in Section 3(o).

"Affiliate" shall have the meaning ascribed to such term in Section 3(n).

"Applicable Time" shall mean, with respect to any Shares, the time of sale of such Shares pursuant to this Agreement or any relevant Terms Agreement.

"Base Prospectus" shall mean the base prospectus contained in the Registration Statement at the Execution Time.

"Board" shall have the meaning ascribed to such term in Section 2(b)(iii).

"Broker Fee" shall have the meaning ascribed to such term in Section 2(b)(v).

"Business Day" shall mean any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, that, for purposes of clarity, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

"Commission" shall mean the United States Securities and Exchange Commission.

"Common Stock" shall have the meaning ascribed to such term in Section 2.

"Common Stock Equivalents" shall have the meaning ascribed to such term in Section 3(g).

"Company Counsel" shall have the meaning ascribed to such term in Section 4(l).

"DTC" shall have the meaning ascribed to such term in Section 2(b)(vii).

"Effective Date" shall mean each date and time that the Registration Statement and any post-effective amendment or amendments thereto became or becomes effective.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Execution Time" shall mean the date and time that this Agreement is executed and delivered by the parties hereto.

"Free Writing Prospectus" shall mean a free writing prospectus, as defined in Rule 405.

"GAAP" shall have the meaning ascribed to such term in Section 3(m).

"Incorporated Documents" shall mean the documents or portions thereof filed with the Commission on or prior to the Effective Date that are incorporated by reference in the Registration Statement or the Prospectus and any documents or portions thereof filed with the Commission after the Effective Date that are deemed to be incorporated by reference in the Registration Statement or the Prospectus.

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3(u).

"Issuer Free Writing Prospectus" shall mean an issuer free writing prospectus, as defined in Rule 433.

"Losses" shall have the meaning ascribed to such term in Section 7(d).

"Material Adverse Effect" shall have the meaning ascribed to such term in Section 3(b).

"Material Permits" shall have the meaning ascribed to such term in Section 3(s).

"Net Proceeds" shall have the meaning ascribed to such term in Section 2(b)(v).

"Permitted Free Writing Prospectus" shall have the meaning ascribed to such term in Section 4(g).

"Placement" shall have the meaning ascribed to such term in Section 2(c).

"Proceeding" shall have the meaning ascribed to such term in Section 3(b).

"Prospectus" shall mean the Base Prospectus, as supplemented by the most recently filed Prospectus Supplement related to the Shares.

"Prospectus Supplement" shall mean each prospectus supplement relating to the Shares prepared and filed pursuant to Rule 424(b) from time to time.

"Registration Statement" shall mean the shelf registration statement (File Number 333-256797) on Form S-3, including exhibits and financial statements, the Base Prospectus and any prospectus supplement relating to the Shares that is filed with the Commission pursuant to Rule 424(b) and deemed part of such registration statement pursuant to Rule 430B, as amended on each Effective Date and, in the event any post-effective amendment thereto becomes effective, shall also mean such registration statement as so amended. Any reference herein to the Registration Statement, the Base Prospectus, the Prospectus Supplement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the Incorporated Documents

"Representation Date" shall have the meaning ascribed to such term in Section 4(k).

"Required Approvals" shall have the meaning ascribed to such term in Section 3(e).

"Rule 158", "Rule 164", "Rule 172", "Rule 173", "Rule 405", "Rule 415", "Rule 424", "Rule 430B" and "Rule 433" refer to such rules under the Act.

"Sales Notice" shall have the meaning ascribed to such term in Section 2(b)(i).

"SEC Reports" shall have the meaning ascribed to such term in Section 3(m).

"Settlement Date" shall have the meaning ascribed to such term in Section 2(b)(vii).

"Subsidiary" shall have the meaning ascribed to such term in Section 3(a).

"Terms Agreement" shall have the meaning ascribed to such term in Section 2(a).

"Time of Delivery" shall have the meaning ascribed to such term in Section 2(c).

"Trading Day" means a day on which the Trading Market is open for trading.

"Trading Market" means the Nasdaq Capital Market.

2. Sale and Delivery of Shares. The Company proposes to issue and sell through or to the Manager, as sales agent and/or principal, from time to time during the term of this Agreement and on the terms set forth herein, up to the lesser of such number of shares (the "Shares") of the Company's common stock, $0.0001 par value per share ("Common Stock"), that does not exceed (a) the number or dollar amount of shares of Common Stock registered on the Registration Statement, pursuant to which the offering is being made, (b) the number of authorized but unissued shares of Common Stock (less the number of shares of Common Stock issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), or (c) the number or dollar amount of shares of Common Stock that would cause the Company or the offering of the Shares to not satisfy the eligibility and transaction requirements for use of Form S-3, including, if applicable, General Instruction I.B.6 of Registration Statement on Form S-3 (the lesser of (a), (b) and (c), the "Maximum Amount"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 2 on the number and aggregate sales price of Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Manager shall have no obligation in connection with such compliance.

(a) Appointment of Manager as Selling Agent; Terms Agreement. For purposes of selling the Shares through the Manager, the Company hereby appoints the Manager as exclusive agent of the Company for the purpose of selling the Shares of the Company pursuant to this Agreement and the Manager agrees to use its commercially reasonable efforts to sell the Shares on the terms and subject to the conditions stated herein. The Company agrees that, whenever it determines to sell the Shares directly to the Manager as principal, it will enter into a separate agreement (each, a "Terms Agreement") in substantially the form of Annex I hereto, relating to such sale in accordance with Section 2 of this Agreement.

(b) Agent Sales. Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company will issue and agrees to sell Shares from time to time through the Manager, acting as sales agent, and the Manager agrees to use its commercially reasonable efforts to sell, as sales agent for the Company, on the following terms:

(i) The Shares are to be sold on a daily basis or otherwise as shall be agreed to by the Company and the Manager on any day that (A) is a Trading Day, (B) the Company has instructed the Manager by telephone (confirmed promptly by electronic mail) to make such sales ("Sales Notice") and (C) the Company has satisfied its obligations under Section 6 of this Agreement. Pursuant to such Sales Notice, the Company will designate the maximum amount of the Shares to be sold by the Manager daily (subject to the limitations set forth in Section 2(d)) and the minimum price per Share at which such Shares may be sold. Subject to the terms and conditions hereof, the Manager shall use its commercially reasonable efforts to sell on a particular day all of the Shares designated for sale by the Company on such day. The gross sales price of the Shares sold under this Section 2(b) shall be the market price for the shares of Common Stock sold by the Manager under this Section 2(b) on the Trading Market at the time of sale of such Shares.

(ii) The Company acknowledges and agrees that (A) there can be no assurance that the Manager will be successful in selling the Shares, (B) the Manager will incur no liability or obligation to the Company or any other person or entity if it does not sell the Shares for any reason other than a failure by the Manager to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Shares as required under this Agreement, and (C) the Manager shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Manager and the Company pursuant to a Terms Agreement.

(iii) The Company shall not authorize the issuance and sale of, and the Manager shall not be obligated to use its commercially reasonable efforts to sell, any Share at a price lower than the minimum price therefor designated from time to time by the Company's Board of Directors (the "Board"), or a duly authorized committee thereof, or such duly authorized officers of the Company, and notified to the Manager in writing. The Company or the Manager may, upon notice to the other party hereto by telephone (confirmed promptly by electronic mail), suspend the offering of the Shares for any reason and at any time; provided, however, that such suspension or termination shall not affect or impair the parties' respective obligations with respect to the Shares sold hereunder prior to the giving of such notice.

(iv) The Manager may sell Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 under the Act, including without limitation sales made directly on the Trading Market, on any other existing trading market for the Common Stock or to or through a market maker. The Manager may also sell Shares in privately negotiated transactions, provided that the Manager receives the Company's prior written approval for any sales in privately negotiated transactions and if so provided in the "Plan of Distribution" section of the Prospectus Supplement or a supplement to the Prospectus Supplement or a new Prospectus Supplement disclosing the terms of such privately negotiated transaction.

(v) The compensation to the Manager for sales of the Shares under this Section 2(b) shall be a placement fee of 3.0% of the gross sales price of the Shares sold pursuant to this Section 2(b) ("Broker Fee"). The foregoing rate of compensation shall not apply when the Manager acts as principal, in which case the Company may sell Shares to the Manager as principal at a price agreed upon at the relevant Applicable Time pursuant to a Terms Agreement. The remaining proceeds, after deduction of the Broker Fee and deduction of any transaction fees imposed by any clearing firm, execution broker, or governmental or self-regulatory organization in respect of such sales, shall constitute the net proceeds to the Company for such Shares (the "Net Proceeds").

(vi) The Manager shall provide written confirmation (which may be by electronic mail) to the Company following the close of trading on the Trading Market each day in which the Shares are sold under this Section 2(b) setting forth the number of the Shares sold on such day, the aggregate gross sales proceeds and the Net Proceeds to the Company, and the compensation payable by the Company to the Manager with respect to such sales.

(vii) Unless otherwise agreed between the Company and the Manager in writing, settlement for sales of the Shares pursuant to this Section 2(b) will occur at 10:00 a.m. (New York City time) on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "Settlement Date"). On or before the Trading Day prior to each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Manager's or its designee's account (provided that the Manager shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company ("DTC") through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto, which Shares in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Manager will deliver the related Net Proceeds in same day funds to an account designated by the Company. The Company agrees that, if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Shares on a Settlement Date, in addition to and in no way limiting the rights and obligations set forth in Section 7 hereto, the Company will (i) hold the Manager harmless against any loss, claim, damage, or reasonable, documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company, and (ii) pay to the Manager any commission, discount or other compensation to which the Manager would otherwise have been entitled absent such default.

(viii) At each Applicable Time, Settlement Date and Representation Date, the Company shall be deemed to have affirmed each representation and warranty contained in this Agreement as if such representation and warranty were made as of such date, modified as necessary to relate to the Registration Statement and the Prospectus as amended as of such date. Any obligation of the Manager to use its commercially reasonable efforts to sell the Shares on behalf of the Company shall be subject to the continuing accuracy of the representations and warranties of the Company herein, to the performance by the Company of its obligations hereunder and to the continuing satisfaction of the additional conditions specified in Section 6 of this Agreement.

(ix) If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, 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" and the record date for the determination of stockholders entitled to receive the Distribution, the "Record Date"), the Company hereby covenants and agrees that, in connection with any sales of Shares pursuant to a Sales Notice on the Record Date, the Company shall issue and deliver such Shares to the Manager on the Record Date and the Record Date shall be the Settlement Date and the Company shall cover any additional costs of the Manager in connection with the delivery of Shares on the Record Date.

(c) Term Sales. If the Company wishes to sell the Shares pursuant to this Agreement but other than as set forth in Section 2(b) of this Agreement (each, a "Placement"), the Company will notify the Manager of the proposed terms of such Placement. If the Manager, acting as principal, wishes to accept such proposed terms (which it may decline to do for any reason in its sole discretion) or, following discussions with the Company wishes to accept amended terms, the Manager and the Company will enter into a Terms Agreement setting forth the terms of such Placement. The terms set forth in a Terms Agreement will not be binding on the Company or the Manager unless and until the Company and the Manager have each executed such Terms Agreement accepting all of the terms of such Terms Agreement. In the event of a conflict between the terms of this Agreement and the terms of a Terms Agreement, the terms of such Terms Agreement will control. A Terms Agreement may also specify certain provisions relating to the reoffering of such Shares by the Manager. The commitment of the Manager to purchase the Shares pursuant to any Terms Agreement shall be deemed to have been made on the basis of the representations and warranties of the Company herein contained and shall be subject to the terms and conditions herein set forth. Each Terms Agreement shall specify the number of the Shares to be purchased by the Manager pursuant thereto, the price to be paid to the Company for such Shares, any provisions relating to rights of, and default by, underwriters acting together with the Manager in the reoffering of the Shares, and the time and date (each such time and date being referred to herein as a "Time of Delivery") and place of delivery of and payment for such Shares. Such Terms Agreement shall also specify any requirements for opinions of counsel, accountants' letters and officers' certificates pursuant to Section 6 of this Agreement and any other information or documents required by the Manager. For the avoidance of any doubt, this Section 2(c) does not convey any right of first refusal onto the Manager or any other rights with respect to any other offerings of the Shares outside of this Agreement.

(d) Maximum Number of Shares. Under no circumstances shall the Company cause or request the offer or sale of any Shares if, after giving effect to the sale of such Shares, the aggregate amount of Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Shares under this Agreement, the Maximum Amount, (B) the amount available for offer and sale under the currently effective Registration Statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Board, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Manager in writing. Under no circumstances shall the Company cause or request the offer or sale of any Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Board, a duly authorized committee thereof or a duly authorized executive officer, and notified to the Manager in writing. Further, under no circumstances shall the Company cause or permit the aggregate offering amount of Shares sold pursuant to this Agreement to exceed the Maximum Amount.

(e) Regulation M Notice. Unless the exceptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are satisfied with respect to the Shares, if required by Regulation M, the Company shall give the Manager at least one (1) Business Day's prior notice of its intent to sell any Shares in order to allow the Manager time to comply with Regulation M.

3. Representations and Warranties. The Company represents and warrants to, and agrees with, the Manager at the Execution Time and on each such time the following representations and warranties are repeated or deemed to be made pursuant to this Agreement as follows:

(a) Subsidiaries. All of the direct and indirect subsidiaries (individually, a "Subsidiary") of the Company are set forth in the SEC Reports. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any "Liens" (which for purposes of this Agreement shall mean a lien, charge, security interest, encumbrance, right of first refusal, preemptive right or other restriction), and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of this Agreement, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, from that set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement, the Prospectus or the Incorporated Documents, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under this Agreement (any of (i), (ii) or (iii), a "Material Adverse Effect") and no "Proceeding" (which for purposes of this Agreement shall mean any action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or, to the Company's knowledge, threatened) has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization and Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder. The execution and delivery of this Agreement by the Company and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board or the Company's stockholders in connection herewith other than in connection with the Required Approvals. This Agreement has been duly executed and delivered by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares and the consummation by it of the transactions contemplated hereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other "Person" (defined as an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind, including the Trading Market) in connection with the execution, delivery and performance by the Company of this Agreement, other than (i) the filings required by this Agreement, (ii) the filing with the Commission of the Prospectus Supplement, (iii) the filing of application(s) to and approval by the Trading Market for the listing of the Shares for trading thereon in the time and manner required thereby, and (iv) such filings as are required to be made under applicable state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("FINRA") (collectively, the "Required Approvals").

(f) Issuance of Shares. The Shares are duly authorized and, when issued and paid for in accordance with this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement based on the price per share of Common Stock on the Trading Market as of the date that this representation is made. The issuance by the Company of the Shares has been registered under the Act and all of the Shares are freely transferable and tradable by the purchasers thereof without restriction (other than any restrictions arising solely from an act or omission of such a purchaser). The Shares are being issued pursuant to the Registration Statement and the issuance of the Shares has been registered by the Company under the Act. The "Plan of Distribution" section within the Registration Statement permits the issuance and sale of the Shares as contemplated by this Agreement. Upon receipt of the Shares, the purchasers of such Shares will have good and marketable title to such Shares and the Shares will be freely tradable on the Trading Market.

(g) Capitalization. The capitalization of the Company is as set forth in the SEC Reports. The Company has not issued any capital stock since its most recently filed SEC Report, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plan and pursuant to the conversion and/or exercise of securities exercisable, exchangeable or convertible into Common Stock ("Common Stock Equivalents") outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by this Agreement. Except as set forth in the SEC Reports, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Shares will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person. Except as set forth in the SEC Reports, the Registration Statement or the Prospectus, there are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board or others is required for the issuance and sale of the Shares. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) Registration Statement. The Company meets the requirements for use of Form S-3 under the Act and has prepared and filed with the Commission the Registration Statement, including a related Base Prospectus, for registration under the Act of the offering and sale of the Shares. Such Registration Statement is effective and available for the offer and sale of the Shares as of the date hereof. As filed, the Prospectus contains all information required by the Act and the rules thereunder, and, except to the extent the Manager shall agree in writing to a modification, shall be in all substantive respects in the form furnished to the Manager prior to the Execution Time or prior to any such time this representation is repeated or deemed to be made. The Registration Statement, at the Execution Time, each such time this representation is repeated or deemed to be made, and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172, 173 or any similar rule) in connection with any offer or sale of the Shares, meets the requirements set forth in Rule 415(a)(1)(x). The initial Effective Date of the Registration Statement was not earlier than the date three years before the Execution Time. The Company meets the transaction requirements with respect to the aggregate market value of securities being sold pursuant to this offering and during the twelve (12) months prior to this offering, as set forth in General Instruction I.B.6 of Form S-3, if applicable.

(i) Accuracy of Incorporated Documents. The Incorporated Documents, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the rules thereunder, and none of the Incorporated Documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Registration Statement, the Base Prospectus, the Prospectus Supplement or the Prospectus, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the rules thereunder, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(j) Ineligible Issuer. (i) At the earliest time after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2)) of the Shares and (ii) as of the Execution Time and on each such time this representation is repeated or deemed to be made (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405), without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(k) Free Writing Prospectus. The Company is eligible to use Issuer Free Writing Prospectuses. Each Issuer Free Writing Prospectus does not include any information the substance of which conflicts with the information contained in the Registration Statement, including any Incorporated Documents and any prospectus supplement deemed to be a part thereof that has not been superseded or modified; and each Issuer Free Writing Prospectus does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Manager specifically for use therein. Any Issuer Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) has been, or will be, filed with the Commission in accordance with the requirements of the Act and the rules thereunder. Each Issuer Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) or that was prepared by or behalf of or used by the Company complies or will comply in all material respects with the requirements of the Act and the rules thereunder. The Company will not, without the prior consent of the Manager (such consent not to be unreasonably withheld, conditioned or delayed),, prepare, use or refer to, any Issuer Free Writing Prospectuses.

(l) Proceedings Related to Registration Statement. The Registration Statement is not the subject of a pending proceeding or examination under Section 8(d) or 8(e) of the Act, and the Company is not the subject of a pending proceeding under Section 8A of the Act in connection with the offering of the Shares. The Company has not received any notice that the Commission has issued or intends to issue a stop-order with respect to the Registration Statement or that the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, or intends or has threatened in writing to do so.

(m) SEC Reports. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Prospectus and the Prospectus Supplement, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(n) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in a subsequent SEC Report filed prior to the date hereof, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any material liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or "Affiliate" (defined as any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 144 under the Act), except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(o) Litigation. Except as set forth in the SEC Reports, there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action"). None of the Actions set forth in the SEC Reports, (i) adversely affects or challenges the legality, validity or enforceability of this Agreement or the Shares or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Except as set forth on Schedule 3(o), neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Act.

(p) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(r) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(s) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(t) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance, except where failure to be in compliance could not reasonably be expected to have a Material Adverse Effect.

(u) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). Except as set forth in the Company's SEC Reports, none of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(v) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(w) Affiliate Transactions. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(x) Sarbanes Oxley Compliance. The Company and the Subsidiaries are in compliance in all material respects with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(y) Certain Fees. Other than payments to be made to the Manager, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by this Agreement. The Manager shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by this Agreement.

(z) No Other Sales Agency Agreement. The Company has not entered into any other sales agency agreements or other similar arrangements with any agent or any other representative in respect of at the market offerings of the Shares.

(aa) Listing and Maintenance Requirements. The Common Stock is listed on the Trading Market and the issuance of the Shares as contemplated by this Agreement does not contravene the rules and regulations of the Trading Market. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as set forth in the SEC Reports, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market, except for the notice received by the Company on May 31, 2022 from the Listing Qualifications Department of the Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(bb) Application of Takeover Protections. Except as set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus, the Company and the Board have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Shares.

(cc) Solvency. Based on the consolidated financial condition of the Company as of the date hereof, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the date hereof. The SEC Reports sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(dd) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(ee) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

(ff) Accountants. The Company's accounting firm is set forth in the SEC Reports. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2022.

(gg) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Manager in connection with the Shares.

(hh) As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a "Product"), such Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(ii) Stock Option Plans. Each stock option granted by the Company under the Company's stock option plan was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(jj) Cybersecurity. (i)(x) There has been no security breach or other compromise of or relating to any of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "IT Systems and Data") and (y) the Company and the Subsidiaries have not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to its IT Systems and Data; (ii) the Company and the Subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iv) the Company and the Subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices.

(kk) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(ll) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon the Manager's request.

(mm) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(nn) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(oo) FINRA Member Shareholders. Except as set forth on Schedule 3(nn), there are no affiliations with any FINRA member firm among the Company's officers, directors or, to the knowledge of the Company, any five percent (5%) or greater stockholder of the Company, except as set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus.

4. Agreements. The Company agrees with the Manager that:

(a) Right to Review Amendments and Supplements to Registration Statement and Prospectus. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act in connection with the offering or the sale of Shares, the Company will not file any amendment to the Registration Statement or supplement (including any Prospectus Supplement) to the Base Prospectus unless the Company has furnished to the Manager a copy for its review prior to filing and will not file any such proposed amendment or supplement to which the Manager reasonably objects. The Company has properly completed the Prospectus, in a form approved by the Manager, and filed such Prospectus, as amended at the Execution Time, with the Commission pursuant to the applicable paragraph of Rule 424(b) by the Execution Time and will cause any supplement to the Prospectus to be properly completed, in a form approved by the Manager, and will file such supplement with the Commission pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed thereby and will provide evidence reasonably satisfactory to the Manager of such timely filing. The Company will promptly advise the Manager (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the Commission pursuant to Rule 424(b), (ii) when, during any period when the delivery of a prospectus (whether physically or through compliance with Rule 172, 173 or any similar rule) is required under the Act in connection with the offering or sale of the Shares, any amendment to the Registration Statement shall have been filed or become effective (other than any annual report of the Company filed pursuant to Section 13(a) or 15(d) of the Exchange Act), (iii) of any request by the Commission or its staff for any amendment of the Registration Statement, or for any supplement to the Prospectus or for any additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any notice objecting to its use or the institution or threatening of any proceeding for that purpose and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its best efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or a new registration statement and using its best efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) Subsequent Events. If, at any time on or after an Applicable Time but prior to the related Settlement Date, any event occurs as a result of which the Registration Statement or Prospectus would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Manager so that any use of the Registration Statement or Prospectus may cease until such are amended or supplemented; (ii) amend or supplement the Registration Statement or Prospectus to correct such statement or omission; and (iii) supply any amendment or supplement to the Manager in such quantities as the Manager may reasonably request.

(c) Notification of Subsequent Filings. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act, any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend the Registration Statement, file a new registration statement or supplement the Prospectus to comply with the Act or the Exchange Act or the respective rules thereunder, including in connection with use or delivery of the Prospectus, the Company promptly will (i) notify the Manager of any such event, (ii) subject to Section 4(a), prepare and file with the Commission an amendment or supplement or new registration statement which will correct such statement or omission or effect such compliance, (iii) use its best efforts to have any amendment to the Registration Statement or new registration statement declared effective as soon as practicable in order to avoid any disruption in use of the Prospectus and (iv) supply any supplemented Prospectus to the Manager in such quantities as the Manager may reasonably request.

(d) Earnings Statements. As soon as practicable, the Company will make generally available to its security holders and to the Manager an earnings statement or statements of the Company and its Subsidiaries which will satisfy the provisions of Section 11(a) of the Act and Rule 158.

(e) Delivery of Registration Statement. Upon the request of the Manager, the Company will furnish to the Manager and counsel for the Manager, without charge, signed copies of the Registration Statement (including exhibits thereto) and, so long as delivery of a prospectus by the Manager or dealer may be required by the Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule), as many copies of the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Manager may reasonably request. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) Qualification of Shares. The Company will arrange, if necessary, for the qualification of the Shares for sale under the laws of such jurisdictions as the Manager may designate and will maintain such qualifications in effect so long as required for the distribution of the Shares; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Shares, in any jurisdiction where it is not now so subject.

(g) Free Writing Prospectus. The Company agrees that, unless it has or shall have obtained the prior written consent of the Manager (such consent not to be unreasonably withheld, conditioned or delayed), and the Manager agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, it has not made and will not make any offer relating to the Shares that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus" (as defined in Rule 405) required to be filed by the Company with the Commission or retained by the Company under Rule 433. Any such free writing prospectus consented to by the Manager or the Company is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company agrees that (i) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (ii) it has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping.

(h) Subsequent Equity Issuances. The Company shall not deliver any Sales Notice hereunder (and any Sales Notice previously delivered shall not apply during such three Business Days) for at least three (3) Business Days prior to any date on which the Company or any Subsidiary offers, sells, issues, contracts to sell, contracts to issue or otherwise disposes of, directly or indirectly, any other shares of Common Stock or any Common Stock Equivalents (other than the Shares), subject to Manager's right to waive this obligation, which waiver shall not be unreasonably withheld, conditioned or delayed, provided that, without compliance with the foregoing obligation, the Company may issue and sell Common Stock pursuant to any employee equity plan, stock ownership plan or dividend reinvestment plan of the Company in effect at the Execution Time and the Company may issue Common Stock issuable upon the conversion or exercise of Common Stock Equivalents outstanding at the Execution Time.

(i) Market Manipulation. Until the termination of this Agreement, the Company will not take, directly or indirectly, any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation in violation of the Act, Exchange Act or the rules and regulations thereunder of the price of any security of the Company to facilitate the sale or resale of the Shares or otherwise violate any provision of Regulation M under the Exchange Act.

(j) Notification of Incorrect Certificate. The Company will, at any time during the term of this Agreement, as supplemented from time to time, advise the Manager immediately after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect any opinion, certificate, letter and other document provided to the Manager pursuant to Section 6 herein.

(k) Certification of Accuracy of Disclosure. Upon commencement of the offering of the Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than thirty (30) Trading Days), and each time that (i) the Registration Statement or Prospectus shall be amended or supplemented, other than by means of Incorporated Documents, (ii) the Company files its Annual Report on Form 10-K under the Exchange Act, (iii) the Company files its quarterly reports on Form 10-Q under the Exchange Act, (iv) the Company files a Current Report on Form 8-K containing amended financial information (other than information that is furnished and not filed), if the Manager reasonably determines that the information in such Form 8-K is material, or (v) the Shares are delivered to the Manager as principal at the Time of Delivery pursuant to a Terms Agreement (such commencement or recommencement date and each such date referred to in (i), (ii), (iii), (iv) and (v) above, a "Representation Date"), unless waived by the Manager, the Company shall furnish or cause to be furnished to the Manager forthwith a certificate dated and delivered on the Representation Date, in form reasonably satisfactory to the Manager to the effect that the statements contained in the certificate referred to in Section 6 of this Agreement which were last furnished to the Manager are true and correct at the Representation Date, as though made at and as of such date (except that such statements shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented to such date) or, in lieu of such certificate, a certificate of the same tenor as the certificate referred to in said Section 6, modified as necessary to relate to the Registration Statement and the Prospectus as amended and supplemented to the date of delivery of such certificate.

(l) Bring Down Opinions; Negative Assurance. At each Representation Date, unless waived by the Manager, the Company shall furnish or cause to be furnished forthwith to the Manager and to counsel to the Manager a written opinion of counsel to the Company ("Company Counsel") addressed to the Manager and dated and delivered on such Representation Date, in form and substance reasonably satisfactory to the Manager, including a negative assurance representation.

(m) Auditor Bring Down "Comfort" Letter. At each Representation Date, unless waived by the Manager, the Company shall cause (1) the Company's auditors (the "Accountants"), or other independent accountants satisfactory to the Manager forthwith to furnish the Manager a letter, and (2) the Chief Financial Officer of the Company forthwith to furnish the Manager a certificate, in each case dated on such Representation Date, in form satisfactory to the Manager, of the same tenor as the letters and certificate referred to in Section 6 of this Agreement but modified to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letters and certificate; provided, however, that the Company will not be required to cause the Accountants to furnish such letters to the Manager in connection with the filing of a Current Report on Form 8-K unless (i) such Current Report on Form 8-K is filed at any time during which a prospectus relating to the Shares is required to be delivered under the Act and (ii) the Manager has requested such letter based upon the event or events reported in such Current Report on Form 8-K.

(n) Due Diligence Session. Upon commencement of the offering of the Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than thirty (30) Trading Days), and at each Representation Date, the Company will conduct a due diligence session, in form and substance, reasonably satisfactory to the Manager, which shall include representatives of management and Accountants. The Company shall cooperate timely with any reasonable due diligence request from or review conducted by the Manager or its agents from time to time in connection with the transactions contemplated by this Agreement, including, without limitation, providing information and available documents and access to appropriate corporate officers and the Company's agents during regular business hours, and timely furnishing or causing to be furnished such certificates, letters and opinions from the Company, its officers and its agents, as the Manager may reasonably request.

(o) Acknowledgment of Trading. The Company consents to the Manager trading in the Common Stock for the Manager's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement or pursuant to a Terms Agreement.

(p) Disclosure of Shares Sold. The Company will disclose in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, the number of Shares sold through the Manager under this Agreement, the Net Proceeds to the Company and the compensation paid by the Company with respect to sales of Shares pursuant to this Agreement during the relevant quarter; and, if required by any subsequent change in Commission policy or request, more frequently by means of a Current Report on Form 8-K or a further Prospectus Supplement.

(q) Rescission Right. If to the knowledge of the Company, the conditions set forth in Section 6 shall not have been satisfied as of the applicable Settlement Date, the Company will offer to any person who has agreed to purchase Shares from the Company as the result of an offer to purchase solicited by the Manager the right to refuse to purchase and pay for such Shares.

(r) Bring Down of Representations and Warranties. Each acceptance by the Company of an offer to purchase the Shares hereunder, and each execution and delivery by the Company of a Terms Agreement, shall be deemed to be an affirmation to the Manager that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct in all material respects as of the date of such acceptance or of such Terms Agreement as though made at and as of such date, and an undertaking that such representations and warranties will be true and correct as of the Settlement Date for the Shares relating to such acceptance or as of the Time of Delivery relating to such sale, as the case may be, as though made at and as of such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(s) Reservation of Shares. The Company shall ensure that there are at all times sufficient shares of Common Stock to provide for the issuance, free of any preemptive rights, out of its authorized but unissued shares of Common Stock or shares of Common Stock held in treasury, of the maximum aggregate number of Shares authorized for issuance by the Board pursuant to the terms of this Agreement. The Company will use its commercially reasonable efforts to cause the Shares to be listed for trading on the Trading Market and to maintain such listing.

(t) Obligation Under Exchange Act. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act, the Company will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and the regulations thereunder.

(u) DTC Facility. The Company shall cooperate with Manager and use its reasonable efforts to permit the Shares to be eligible for clearance and settlement through the facilities of DTC.

(v) Use of Proceeds. The Company will apply the Net Proceeds from the sale of the Shares in the manner set forth in the Prospectus.

(w) Filing of Prospectus Supplement. If any sales are made pursuant to this Agreement which are not made in "at the market" offerings as defined in Rule 415, including, without limitation, any Placement pursuant to a Terms Agreement, the Company shall file a Prospectus Supplement describing the terms of such transaction, the amount of Shares sold, the price thereof, the Manager's compensation, and such other information as may be required pursuant to Rule 424 and Rule 430B, as applicable, within the time required by Rule 424.

(x) Additional Registration Statement. To the extent that the Registration Statement is not available for the sales of the Shares as contemplated by this Agreement, the Company shall file a new registration statement with respect to any additional shares of Common Stock necessary to complete such sales of the Shares and shall cause such registration statement to become effective as promptly as practicable. After the effectiveness of any such registration statement, all references to "Registration Statement" included in this Agreement shall be deemed to include such new registration statement, including all documents incorporated by reference therein pursuant to Item 12 of Form S-3, and all references to "Base Prospectus" included in this Agreement shall be deemed to include the final form of prospectus, including all documents incorporated therein by reference, included in any such registration statement at the time such registration statement became effective.

5. Payment of Expenses. The Company agrees to pay the costs and expenses incident to the performance of its obligations under this Agreement, whether or not the transactions contemplated hereby are consummated, including without limitation: (i) the preparation, printing or reproduction and filing with the Commission of the Registration Statement (including financial statements and exhibits thereto), the Prospectus and each Issuer Free Writing Prospectus, and each amendment or supplement to any of them; (ii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, the Prospectus, and each Issuer Free Writing Prospectus, and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Shares; (iii) the preparation, printing, authentication, issuance and delivery of certificates for the Shares, including any stamp or transfer taxes in connection with the original issuance and sale of the Shares; (iv) the printing (or reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Shares; (v) the registration of the Shares under the Exchange Act, if applicable, and the listing of the Shares on the Trading Market; (vi) any registration or qualification of the Shares for offer and sale under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Manager relating to such registration and qualification); (vii) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Shares; (viii) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; (ix) the filing fee under FINRA Rule 5110; (x) the reasonable fees and expenses of the Manager's counsel, not to exceed $70,000 and up to $3,500 quarterly thereafter; and (xi) all other costs and expenses incident to the performance by the Company of its obligations hereunder.

6. Conditions to the Obligations of the Manager. The obligations of the Manager under this Agreement and any Terms Agreement shall be subject to (i) the accuracy of the representations and warranties on the part of the Company contained herein as of the Execution Time, each Representation Date, and as of each Applicable Time, Settlement Date and Time of Delivery, (ii) the performance by the Company of its obligations hereunder and (iii) the following additional conditions:

(a) Filing of Prospectus Supplement. The Prospectus, and any supplement thereto, required by Rule 424 to be filed with the Commission have been filed in the manner and within the time period required by Rule 424(b) with respect to any sale of Shares; each Prospectus Supplement shall have been filed in the manner required by Rule 424(b) within the time period required hereunder and under the Act; any other material required to be filed by the Company pursuant to Rule 433(d) under the Act, shall have been filed with the Commission within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) Delivery of Opinion. The Company shall have caused the Company Counsel to furnish to the Manager, to the extent requested by the Manager and upon reasonable advance notice in connection with any offering of the Shares, its opinion and negative assurance statement, dated as of such date and addressed to the Manager in form and substance acceptable to the Manager.

(c) Delivery of Officer's Certificate. The Company shall have furnished or caused to be furnished to the Manager, to the extent requested by the Manager and upon reasonable advance notice in connection with any offering of the Shares, a certificate of the Company signed by the Chief Executive Officer or the President and the principal financial or accounting officer of the Company, dated as of such date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the Prospectus, any Prospectus Supplement and any documents incorporated by reference therein and any supplements or amendments thereto and this Agreement and that:

(i) the representations and warranties of the Company in this Agreement are true and correct on and as of such date with the same effect as if made on such date and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to such date;

(ii) no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and

(iii) since the date of the most recent financial statements included in the Registration Statement, the Prospectus and the Incorporated Documents, there has been no Material Adverse Effect on the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Registration Statement and the Prospectus.

(d) Delivery of Accountants' "Comfort" Letter. The Company shall have requested and caused the Accountants to have furnished to the Manager, to the extent requested by the Manager and upon reasonable advance notice in connection with any offering of the Shares, letters (which may refer to letters previously delivered to the Manager), dated as of such date, in form and substance satisfactory to the Manager, confirming that they are independent accountants within the meaning of the Act and the Exchange Act and the respective applicable rules and regulations adopted by the Commission thereunder and that they have performed a review of any unaudited interim financial information of the Company included or incorporated by reference in the Registration Statement and the Prospectus and provide customary "comfort" as to such review in form and substance satisfactory to the Manager.

(e) No Material Adverse Event. Since the respective dates as of which information is disclosed in the Registration Statement, the Prospectus and the Incorporated Documents, except as otherwise stated therein, there shall not have been (i) any change or decrease in previously reported results specified in the letter or letters referred to in paragraph (d) of this Section 6 or (ii) any material change, or any material development involving a material prospective change, in or affecting the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Registration Statement, the Prospectus and the Incorporated Documents (exclusive of any amendment or supplement thereto) the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Manager, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Registration Statement (exclusive of any amendment thereof), the Incorporated Documents and the Prospectus (exclusive of any amendment or supplement thereto).

(f) Payment of All Fees. The Company shall have paid the required Commission filing fees relating to the Shares within the time period required by Rule 456(b)(1)(i) of the Act without regard to the proviso therein and otherwise in accordance with Rules 456(b) and 457(r) of the Act and, if applicable, shall have updated the "Calculation of Registration Fee" table in accordance with Rule 456(b)(1)(ii) either in a post-effective amendment to the Registration Statement or on the cover page of a prospectus filed pursuant to Rule 424(b).

(g) No FINRA Objections. FINRA shall not have raised any objection with respect to the fairness and reasonableness of the terms and arrangements under this Agreement.

(h) Shares Listed on Trading Market. The Shares shall have been listed and admitted and authorized for trading on the Trading Market, and satisfactory evidence of such actions shall have been provided to the Manager.

(i) Other Assurances. Prior to each Settlement Date and Time of Delivery, as applicable, the Company shall have furnished to the Manager such further information, certificates and documents as the Manager may reasonably request.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Manager and counsel for the Manager, this Agreement and all obligations of the Manager hereunder may be canceled at, or at any time prior to, any Settlement Date or Time of Delivery, as applicable, by the Manager. Notice of such cancellation shall be given to the Company in writing or by telephone and confirmed in writing by electronic mail.

The documents required to be delivered by this Section 6 shall be delivered to the office of Ellenoff Grossman & Schole LLP, counsel for the Manager, at 1345 Avenue of the Americas, New York, New York 10105, email: capmkts@egsllp.com, on each such date as provided in this Agreement.

7. Indemnification and Contribution.

(a) Indemnification by Company. The Company agrees to indemnify and hold harmless the Manager, the directors, officers, employees and agents of the Manager and each person who controls the Manager within the meaning of either the Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement for the registration of the Shares as originally filed or in any amendment thereof, or in the Base Prospectus, any Prospectus Supplement, the Prospectus, any Issuer Free Writing Prospectus, or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or result from or relate to any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement, and agrees to reimburse each such indemnified party for any legal or other reasonable and documented out-of-pocket expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by the Manager specifically for inclusion therein. This indemnity agreement will be in addition to any liability that the Company may otherwise have.

(b) Indemnification by Manager. The Manager agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signs the Registration Statement, and each person who controls the Company within the meaning of either the Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to the Manager, but only with reference to written information relating to the Manager furnished to the Company by the Manager specifically for inclusion in the documents referred to in the foregoing indemnity; provided, however, that in no case shall the Manager be responsible for any amount in excess of the Broker Fee applicable to the Shares and paid hereunder. This indemnity agreement will be in addition to any liability which the Manager may otherwise have.

(c) Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 7 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 7, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be reasonably satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ separate counsel (including local counsel), and the indemnifying party shall bear the reasonable and documented fees, costs and out-of-pocket expenses of such separate counsel if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest, (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, (iii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of the institution of such action or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding.

(d) Contribution. In the event that the indemnity provided in paragraph (a), (b) or (c) of this Section 7 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Manager agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other reasonable and documented out-of-pocket expenses reasonably incurred in connection with investigating or defending the same) (collectively "Losses") to which the Company and the Manager may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Manager on the other from the offering of the Shares; provided, however, that in no case shall the Manager be responsible for any amount in excess of the Broker Fee applicable to the Shares and paid hereunder. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Manager severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and of the Manager on the other in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by it, and benefits received by the Manager shall be deemed to be equal to the Broker Fee applicable to the Shares and paid hereunder as determined by this Agreement. Relative fault shall be determined by reference to, among other things, whether any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Manager on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Manager agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (d), no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 7, each person who controls the Manager within the meaning of either the Act or the Exchange Act and each director, officer, employee and agent of the Manager shall have the same rights to contribution as the Manager, and each person who controls the Company within the meaning of either the Act or the Exchange Act, each officer of the Company who shall have signed the Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (d).

8. Termination.

(a) The Company shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time upon five (5) Business Days' prior written notice. Any such termination shall be without liability of any party to any other party except that (i) with respect to any pending sale, through the Manager for the Company, the obligations of the Company, including in respect of compensation of the Manager, shall remain in full force and effect notwithstanding the termination and (ii) the provisions of Sections 5, 6, 7, 8, 9, 10, 12, the second sentence of 13, 14 and 15 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b) The Manager shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that the provisions of Sections 5, 6, 7, 8, 9, 10, 12, the second sentence of 13, 14 and 15 of this Agreement shall remain in full force and effect notwithstanding such termination.

(c) This Agreement shall remain in full force and effect until such date that this Agreement is terminated pursuant to Sections 8(a) or (b) above or otherwise by mutual agreement of the parties, provided that any such termination by mutual agreement shall in all cases be deemed to provide that Sections 5, 6, 7, 8, 9, 10, 12, the second sentence of 13, 14 and 15 shall remain in full force and effect.

(d) Any termination of this Agreement shall be effective on the date specified in such notice of termination, provided that such termination shall not be effective until the close of business on the date of receipt of such notice by the Manager or the Company, as the case may be. If such termination shall occur prior to the Settlement Date or Time of Delivery for any sale of the Shares, such sale of the Shares shall settle in accordance with the provisions of Section 2(b) of this Agreement.

(e) In the case of any purchase of Shares by the Manager pursuant to a Terms Agreement, the obligations of the Manager pursuant to such Terms Agreement shall be subject to termination, in the absolute discretion of the Manager, by prompt oral notice given to the Company prior to the Time of Delivery relating to such Shares, if any, and confirmed promptly by electronic mail, if since the time of execution of the Terms Agreement and prior to such delivery and payment, (i) trading in the Common Stock shall have been suspended by the Commission or the Trading Market or trading in securities generally on the Trading Market shall have been suspended or limited or minimum prices shall have been established on such exchange, (ii) a banking moratorium shall have been declared either by Federal or New York State authorities or (iii) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the sole judgment of the Manager, impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Prospectus (exclusive of any amendment or supplement thereto).

9. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers and of the Manager set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by the Manager or the Company or any of the officers, directors, employees, agents or controlling persons referred to in Section 7, and will survive delivery of and payment for the Shares.

10. Notices. All communications hereunder will be in writing and effective only on receipt, and will be mailed, delivered, or e-mailed to the addresses of the Company and the Manager, respectively, set forth on the signature page hereto.

11. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 7, and no other person will have any right or obligation hereunder.

12. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Shares pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Manager and any affiliate through which it may be acting, on the other, (b) the Manager is acting solely as sales agent and/or principal in connection with the purchase and sale of the Company's securities and not as a fiduciary of the Company and (c) the Company's engagement of the Manager in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether the Manager has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Manager has rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

13. Integration. This Agreement and any Terms Agreement supersede all prior agreements and understandings (whether written or oral) between the Company and the Manager with respect to the subject matter hereof. Notwithstanding anything herein to the contrary, the investment banking agreements, dated August 30, 2022 and February 28, 2023, by and between the Company and the Manager shall continue to be effective and the terms therein shall continue to survive and be enforceable by the Manager in accordance with its terms, provided that, in the event of a conflict between the terms of the letter agreement and this Agreement, the terms of this Agreement shall prevail.

14. Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Manager. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

15. Applicable Law. This Agreement and any Terms Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York. Each of the Company and the Manager: (i) agrees that any legal suit, action or proceeding arising out of or relating to this Agreement shall be instituted exclusively in New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, (ii) waives any objection which it may have or hereafter to the venue of any such suit, action or proceeding, and (iii) irrevocably consents to the exclusive jurisdiction of the New York Supreme Court, County of New York, and the United States District Court for the Southern District of New York in any such suit, action or proceeding. Each of the Company and the Manager further agrees to accept and acknowledge service of any and all process which may be served in any such suit, action or proceeding in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York and agrees that service of process upon the Company mailed by certified mail to the Company's address shall be deemed in every respect effective service of process upon the Company, in any such suit, action or proceeding, and service of process upon the Manager mailed by certified mail to the Manager's address shall be deemed in every respect effective service process upon the Manager, in any such suit, action or proceeding. If either party shall commence an action or proceeding to enforce any provision of this Agreement, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its reasonable attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

16. WAIVER OF JURY TRIAL. THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, ANY TERMS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

17. Counterparts. This Agreement and any Terms Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, which may be delivered in .pdf file via e-mail.

18. Headings. The section headings used in this Agreement and any Terms Agreement are for convenience only and shall not affect the construction hereof.

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If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the Manager.

Very truly yours,

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr.
Name: Nestor Jaramillo, Jr.
Title: President & CEO

Address for Notice:
12988 Valley View Road
Eden Prairie, MN 55344

The foregoing Agreement is hereby confirmed and accepted as of the date first written above.

LADENBURG THALMANN & CO. INC.

By: /s/ Nicholas Stergis
Name: Nicholas Stergis
Title: Managing Director

Address for Notice:

640 Fifth Avenue, 4th Floor
New York, NY 10019
Email:
Attn:

Form of Terms Agreement
ANNEX I
Nuwellis, Inc.
TERMS AGREEMENT

Dear Sirs:

Nuwellis, Inc. (the "Company") proposes, subject to the terms and conditions stated herein and in the At The Market Offering Agreement, dated March __, 2023 (the "At The Market Offering Agreement"), between the Company and Ladenburg Thalmann & Co. Inc. ("Manager"), to issue and sell to Manager the securities specified in the Schedule I hereto (the "Purchased Shares").

Each of the provisions of the At The Market Offering Agreement not specifically related to the solicitation by the Manager, as agent of the Company, of offers to purchase securities is incorporated herein by reference in its entirety, and shall be deemed to be part of this Terms Agreement to the same extent as if such provisions had been set forth in full herein. Each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Terms Agreement and the Time of Delivery, except that each representation and warranty in Section 3 of the At The Market Offering Agreement which makes reference to the Prospectus (as therein defined) shall be deemed to be a representation and warranty as of the date of the At The Market Offering Agreement in relation to the Prospectus, and also a representation and warranty as of the date of this Terms Agreement and the Time of Delivery in relation to the Prospectus as amended and supplemented to relate to the Purchased Shares.

An amendment to the Registration Statement (as defined in the At The Market Offering Agreement), or a supplement to the Prospectus, as the case may be, relating to the Purchased Shares, in the form heretofore delivered to the Manager is now proposed to be filed with the Securities and Exchange Commission.

Subject to the terms and conditions set forth herein and in the At The Market Offering Agreement which are incorporated herein by reference, the Company agrees to issue and sell to the Manager and the latter agrees to purchase from the Company the number of shares of the Purchased Shares at the time and place and at the purchase price set forth in the Schedule I hereto.

If the foregoing is in accordance with your understanding, please sign and return to us a counterpart hereof, whereupon this Terms Agreement, including those provisions of the At The Market Offering Agreement incorporated herein by reference, shall constitute a binding agreement between the Manager and the Company.

NUWELLIS, INC.

By:_____
Name:
Title:

ACCEPTED as of the date first written above.

LADENBURG THALMANN & CO. INC.

By:_____
Name:
Title:

Exhibit 4.13

Nuwellis, Inc.

Description of Securities

General

Nuwellis, Inc. is incorporated in the State of Delaware. The following description summarizes the most important terms of our capital stock. This description is not complete, and we qualify it by referring to our certificate of incorporation, bylaws and certificate of designation of preferences, rights and limitations of Series F Preferred Stock and Series I Preferred Stock, copies of which have been incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and to the applicable provisions of the Delaware General Corporation Law.

Common Stock, $0.0001 par value

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 "-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 "-Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law;"
- the choice of forum provision described below under "-Choice of Forum;"
- the limitations on director liability and indemnification described below under the heading "-Limitation on Liability of Directors and Indemnification;" and

- the super-majority voting requirement to amend our certificate of incorporation described above.

Conversion, Redemption and Preemptive Rights

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

Liquidation, Dissolution and Winding-up

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

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.

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 ("Series F Preferred Stock").

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 then-current conversion price (subject to adjustment described below). As of December 31, 2022, the conversion price was $25.00. 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 Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. 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 Securities Exchange Act of 1934, as amended, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1) (i) promulgated under the Securities Exchange Act of 1934, as amended, any person who acquires Series 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.

Certain Adjustments

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. 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 immediately prior to the consummation of the fundamental transaction or (ii) 130% of the stated value of the Series F Preferred Stock then outstanding on the date of 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 Delaware general corporation law.

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

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

Series I Convertible Preferred Stock. Our board of directors designated 23,157,124 shares of preferred stock as Series I convertible preferred stock, $0.0001 par value ("Series I Preferred Stock").

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

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

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

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

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

Certain Adjustments

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

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

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

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

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

Description of Outstanding Warrants

As of December 31, 2022, there were warrants outstanding to purchase a total of 679,244 shares of our common stock, which were exercisable at prices ranging from $25.00 to $89,040 and are exercisable over a period ranging from immediate to 5.8 years. Certain of these warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants provide that, subject to limited exceptions, a holder will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own over 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, the warrant holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

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

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

- providing for our board of directors to be divided into three classes with staggered three-year terms, with only one class of directors being elected at each annual meeting of our stockholders and the other classes continuing for the remainder of their respective three-year terms;
- authorizing our board of directors to issue from time to time any series of preferred stock and fix the voting powers, designation, powers, preferences and rights of the shares of such series of preferred stock;
- prohibiting stockholders from acting by written consent in lieu of a meeting;
- requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting;
- prohibiting stockholders from calling a special meeting of stockholders;
- requiring a 662⁄3% super-majority stockholder approval in order for stockholders to alter, amend or repeal certain provisions of our certificate of incorporation;
- requiring a 662⁄3% super-majority stockholder approval in order for stockholders to adopt, amend or repeal our bylaws;
- providing that, subject to the rights of the holders of any series of preferred stock to elect additional directors under specified circumstances, neither the board of directors nor any individual director may be removed without cause;
- creating the possibility that our board of directors could prevent a coercive takeover of our Company due to the significant amount of authorized, but unissued shares of our common stock and preferred stock;

- providing that, subject to the rights of the holders of any series of preferred stock, the number of directors shall be fixed from time to time exclusively by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- providing that any vacancies on our board of directors under certain circumstances will be filled only by a majority of our board of directors then in office, even if less than a quorum, and not by the stockholders.

Delaware Law

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

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

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

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

Choice of Forum

Our Fourth Amended and Restated Certificate of Incorporation, as amended, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a claim of 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. 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 Delaware General Corporation Law, 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.

Transfer Agent and Registrar

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

Listing

Our common stock trades on The Nasdaq Capital Market under the symbol "NUWE."

Exhibit 5.1

HONIGMAN.

March 3, 2023

Nuwellis, Inc.
12988 Valley View Road
Eden Prairie, MN 55344

Re: Prospectus Supplement to Registration Statement on Form S-3 (File No. 333-256797)

Ladies and Gentlemen:

We have acted as counsel to Nuwellis, Inc., a Delaware corporation (the "***Company***"), in connection with (i) preparing and filing with the Securities and Exchange Commission (the "***Commission***") pursuant to the Securities Act of 1933, as amended (the "***Securities Act***"), of (a) a Registration Statement on Form S-3 (File No. 333-256797) (such registration statement as amended or supplemented from time to time, the "***Registration Statement***"), declared effective on July 2, 2021, and the prospectus of the Company included in the Registration Statement (the "***Base Prospectus***") and (b) a prospectus supplement to the Base Prospectus, dated as of March 3, 2023 (the "***Prospectus Supplement***"), pertaining to the issuance and sale by the Company of shares of the Company's common stock, par value $0.0001 per share (the "***Common Stock***") of an aggregate indeterminate amount having an aggregate public offering price not to exceed $10,000,000 (the "***Shares***") that may be issued and sold under the At The Market Offering Agreement, dated as of March 3, 2023 (the "***Sales Agreement***"), by and between the Company and Ladenburg Thalmann & Co., Inc., as the manager.

For the purpose of rendering this opinion, we examined originals or copies of such documents as we deemed relevant. In conducting our examination, we assumed, without investigation, the genuineness of all signatures, the correctness of all certificates, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted as certified or photostatic copies, and the authenticity of the originals of such copies, and the accuracy and completeness of all records made available to us by the Company. In addition, in rendering this opinion, we have assumed that the Shares will be offered in the manner and on the terms identified or referred to in the Registration Statement, the Base Prospectus, the Prospectus Supplement, including all supplements and amendments thereto, and the Sales Agreement.

Our opinion is limited solely to matters set forth herein. The law covered by the opinions expressed herein is limited to the federal law of the United States and the Delaware General Corporation Law.

Based upon our examination of such documents and other matters as we deem relevant, we are of the opinion that the Shares covered by the Registration Statement and the Prospectus Supplement have been duly authorized by the Company and, when issued, sold, and delivered by the Company in accordance with, and as described in, the Registration Statement and the Prospectus Supplement and in the manner set forth in the Sales Agreement, against payment therefor, will be validly issued, fully paid and non-assessable.

We hereby consent to the filing of this opinion with the Commission as Exhibit 5.1 to the Company's Current Report on Form 8-K, which is incorporated by reference in the Registration Statement, and to the reference to our firm under the caption "Legal Matters" in the Registration Statement and the Prospectus Supplement. In giving such consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations promulgated thereunder by the Commission.

Very truly yours,

/s/ HONIGMAN LLP

Honigman LLP

PDT/JQW/EAAL/RZK

Exhibit 10.17

SECOND AMENDMENT
TO THE
NUWELLIS, INC.
2017 EQUITY INCENTIVE PLAN

This Second Amendment of the Nuwellis, Inc. 2017 Equity Incentive Plan (this ***"Second Amendment"***) is made and adopted by Nuwellis, Inc., a Delaware corporation (the ***"Company"***), subject to approval by the stockholders of the Company. Following such effective date, any reference to the "Nuwellis, Inc. 2017 Equity Incentive Plan" shall mean the Nuwellis, Inc. 2017 Equity Incentive Plan, as amended hereby. Capitalized terms used herein without definition shall have the meanings assigned to them in the Nuwellis, Inc. 2017 Equity Incentive Plan.

WHEREAS, the Company maintains the Nuwellis, Inc. 2017 Equity Incentive Plan (the ***"Plan"***);

WHEREAS, the Board of Directors of the Company (the *"Board"*) may amend the Plan at any time, pursuant to and subject to Section 2(b) of the Plan, contingent on approval by stockholders of the Company, if stockholder approval is required by applicable securities exchange rules or applicable law; and

WHEREAS, the Board has determined that it is advisable and in the best interest of the Company and its stockholders to amend the Plan to increase the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options to 7,732,755, provided that such shares of Common Stock shall not be subject to adjustment pursuant to the applicable provisions of Section 9(a)(i) of the Plan in connection with the reverse stock split effected by the Company on October 16, 2020 or the first reverse stock split effected by the Company following December 5, 2022.

NOW, THEREFORE, the Plan is hereby amended as follows:

1. **AMENDMENT TO SECTION 3(C).** The second sentence of Section 3(c) of the Plan is hereby amended and restated in its entirety as follows, subject to approval by the stockholders of the Company:

"This Section 3(c) shall not be subject to adjustment pursuant to the applicable provisions of Section 9(a)(i) of the Plan in connection with the reverse stock split effected by the Company on October 16, 2020 or the first reverse stock split effected by the Company following December 5, 2022."

2. **EFFECT ON THE PLAN.** Except as expressly or by necessary implication amended hereby, the Plan shall remain in full force and effect.

IN WITNESS WHEREOF, I hereby certify that the foregoing Second Amendment was duly adopted by the Board of Directors of Nuwellis, Inc. on October 28, 2022.

NUWELLIS, INC.

By: /s/ Neil Ayotte
Name: Neil Ayotte
Title: Senior Vice President, General Counsel, Secretary and Chief Compliance Officer

Exhibit 10.27

NUWELLIS, INC. NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

(Effective January 1, 2023)

On January 26, 2023, upon the recommendation of the Compensation Committee (the "Compensation Committee") of the Board of Directors (the "Board") of Nuwellis, Inc. a Delaware corporation (the "Company"), the Board approved the following compensation policy (this "Policy") for Non-Employee Directors, effective as of January 1, 2023 (the "Effective Date"). For purposes of this Policy, a "Non-Employee Director" is (i) a director of the Company who has not served as an employee or executive officer of the Company or its affiliates or otherwise provided services to the Company or its affiliates in a capacity other than as a director of the Company or its affiliates during the preceding year or (ii) a director of the Company who has previously served, but does not currently serve, as an employee or executive officer of the Company or its affiliates and whom the Board (disregarding the director of the Company referred to in this clause (ii)) has determined is a Non-Employee Director under this Policy.

ANNUAL CASH COMPENSATION

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If a Non-Employee Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer and fee set forth below will be prorated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Non-Employee Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

- Base Annual Retainer for Non-Employee Directors: $45,000
- Additional Base Annual Retainer for additional positions and committee membership:
    - Chair of the Board: $15,000
    - Lead Independent Director: $10,000 • Chair Audit Committee: $15,000
    - Chair Compensation Committee: $10,000
    - Chair Nominating and Governance Committee: $10,000
    - Member Audit Committee: $7,500
    - Member Compensation Committee: $5,000
    - Member Nominating and Governance Committee: $5,000

ANNUAL EQUITY AWARD

Each Non-Employee Director will be eligible to receive compensatory equity awards under the Company's 2013 Non-Employee Directors' Equity Incentive Plan (the "Plan") as consideration for service on the Board. All grants under this Policy will be made automatically in accordance with the terms of this Policy and the Plan, without the need for any additional corporate action by the Board or the Compensation Committee. Vesting of all equity awards granted under this Policy is subject to a Non-Employee Director's Continuous Service (as defined in the Plan) from the date of grant through each applicable vesting date. All equity awards granted under this Policy will be subject to the Company's standard forms of award agreements, as most recently adopted by the Board for use under this Policy. 1Each year on the date of the first regular annual meeting of the Company's stockholders (the "Annual Meeting"), the Company will automatically grant each newly-elected and each continuing Non-Employee Director, an annual equity award with an aggregate value on the date of grant equal to 0.4% of the fully diluted shares of the Company as of December 31 of the prior year (the "Annual Equity Award"). Subject to a Non-Employee Director's Continuous Service, the Annual Equity Award will vest 1/12 of the shares each month, commencing on the one-month anniversary of the date of grant, so that all of the shares will be vested on the one-year anniversary of the date of grant.

PRO-RATA ANNUAL EQUITY AWARD

If an individual first becomes a Non-Employee Director other than at the Annual Meeting, the Company will automatically grant such new Non-Employee Director, on the date that he or she is first elected or appointed to the Board, an annual equity award with an aggregate value on the date of grant equal to the pro rata portion of the Annual Equity Award, which pro rata portion reflects a reduction for each month prior to the date of grant that has elapsed since the preceding Annual Meeting (the "Pro-Rated Annual Equity Award"). Subject to a Non-Employee Director's Continuous Service, the Pro-Rated Annual Equity Award will vest 1/12 of the shares each month, commencing on the one-month anniversary of the date of grant, so that all of the shares will be vested on the one-year anniversary of the date of grant.

EXPENSE REIMBURSEMENT

All Non-Employee Directors will be entitled to reimbursement from the Company for their reasonable travel (including airfare and ground transportation), lodging and meal expenses incident to meetings of the Board or committees thereof. The Company will also reimburse directors for attendance at director continuing education programs that are relevant to their service on the Board and which attendance is pre-approved by the Chair of the Governance and Nominating Committee or the Chair of the Board. The Company will make reimbursement to a Non-Employee Director within a reasonable amount of time following submission by such Non-Employee Director of reasonable written substantiation for the expenses.

Exhibit 10.63

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

LICENSE AND DISTRIBUTION AGREEMENT

This LICENSE AND DISTRIBUTION AGREEMENT (this ***"Agreement"***) is made and entered into effective as of December 27, 2022 (the ***"Effective Date"***) by and between SeaStar Medical Holding Corporation, a Delaware corporation, with a place of business at 3513 Brighton Blvd, Suite 410, Denver, Colorado 80216 (***"Supplier"***), and Nuwellis, Inc., a Delaware corporation, with a place of business at 12988 Valley View Road, Eden Prairie, Minnesota 55344 (***"Distributor"***). Supplier or Distributor may hereinafter be referred to as a ***"Party"*** or collectively as ***"Parties"***.

Recitals

Whereas, Supplier is a medical technology company that has developed the Selective Cytopheretic Device (***"SCD"***), for pediatric and adult acute kidney injury (***"AKI"***) indications;

Whereas, Supplier has submitted an application to the FDA (as defined below) for a Humanitarian Device Exemption (***"HDE"***) for SCD for the treatment of pediatric patients with AKI on continuous renal replacement therapy (***"CRRT"***);

Whereas, Supplier desires to appoint Distributor as the exclusive distributor to promote, advertise, market, distribute and sell the Product (as defined below) in the Territory (as defined below) on the terms and conditions set forth in this Agreement; and

Whereas, Distributor desires to accept such appointment, subject to the terms and conditions set forth in this Agreement.

Agreement

Now, Therefore, in consideration of the promises, covenants, and agreements hereinafter set forth, and certain other valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. Definitions. Capitalized terms used herein, to the extent not otherwise defined, have the meanings specified in Exhibit A attached hereto which are incorporated herein for all purposes.

2. Appointment.

2.1. Appointment; Exclusivity.

2.1.1. Supplier hereby appoints Distributor as its exclusive distributor (even as to Supplier) to market, promote, sell, and distribute the Product in the Territory for the Product's HDE authorized uses and Other Authorized Uses, and Distributor hereby accepts such exclusive appointment and agrees to act as such exclusive distributor in the Territory.

2.1.2. Neither Distributor nor its Affiliates or Permitted Sub-Distributors (as defined below) shall intentionally offer for sale, sell, agree to sell, promote, market, distribute or advertise the Product for use outside of the Territory, or sell the Product to any Third Party who, to the reasonable belief of Distributor or its Affiliates or Permitted Sub-Distributors, intends to do so, or cause to be done, any of the foregoing activities. Distributor shall not make any modifications, alterations, or improvements in or to any of the Products, or the Product's packaging or labelling without the prior written consent of Supplier in each instance. For avoidance of doubt, neither Distributor nor its Affiliates or Permitted Sub-Distributors shall offer for sale, sell, agree to sell, promote, market, distribute or advertise the Product for any use not approved by the FDA or that is not an Other Authorized Use.

2.1.3. Notwithstanding anything to the contrary, in the event that Distributor does not sell at least one hundred and fifty (150) or more units of the Product within the initial eighteen (18) month period following Supplier's receipt of HDE Approval for the Product and the completion of the sales force training conducted in collaboration with Supplier, the appointment by Supplier pursuant to this Section 2.1 shall automatically be converted to a non-exclusive appointment of Distributor and for the remainder of the Term, Supplier shall be entitled to appoint additional Third Parties as distributors of the Product on a non-exclusive basis in the Territory. Distributor shall use best efforts to cooperate with Supplier and complete the sales force training as promptly as possible after HDE Approval for the Product.

2.2. Permitted Sub-Distributors. Except for the permitted dealers or sub-distributors listed on EXHIBIT B (each a ***"Permitted Sub-Distributor"***), which exhibit may be updated from time to time upon written consent of Supplier, Distributor shall not appoint any dealers or sub-distributors to distribute, market and sell any Product anywhere in the Territory. Distributor shall ensure that each of its Permitted Sub-Distributors is bound by written agreement that is consistent with, and subject to the terms and conditions of this Agreement. Distributor shall be solely liable and responsible for the performance of any of its Permitted Sub-Distributors.

2.3. License Grant by Supplier. During the Term, Supplier, on behalf of Supplier and its Affiliates, hereby grants to Distributor a limited non-exclusive, non-transferable and terminable license, under Intellectual Property Rights Controlled by Supplier relating solely to the Product, including without limitation, any and all Product Improvements, solely for Distributor to use, import, market, distribute, sell, and offer to sell the Product within the Territory pursuant to this Agreement and consistent with the HDE Approval. Any Product Improvements created by or on behalf of Distributor in the performance of its obligations under this Agreement shall be owned by Supplier. Except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by a Party to the other Party.

2.4. Right of First Negotiation. During the Term, Supplier hereby agrees to provide Distributor prompt written notice (but in any event, such written notice must be delivered not later than thirty (30) business days following Supplier's receipt of applicable regulatory approvals to commercialize such product) in the event Supplier develops a new or replacement of the Product that is approved or is in the process of being approved by the FDA (the ***"New Product"***). Following Distributor's receipt of such written notification from Supplier, Distributor shall have the first right, by providing Supplier with written notice with thirty (30) days of its receipt of such notice (***"Negotiation Notice"***), to negotiate an amendment to this Agreement or a separate agreement to allow Supplier to be the exclusive distributor of such New Product. During the period commencing on the date of Supplier's receipt of such Negotiation Notice and continuing for sixty (60) days thereafter (***"Negotiation Period"***), the Parties shall negotiate the terms of such amendment or contract in good faith. If the Parties do not agree on terms during the Negotiation Period, Supplier and its Affiliates shall be free to enter into an exclusive or non-exclusive distributor relationship with a Third Party without any further obligation to Distributor.

2.5. License with the Regents of the University of Michigan. During the Term, Supplier shall remain solely liable and responsible to all Third Parties to which Supplier owes any royalty or other payment obligations in connection with the Product, including, without limitation, any amounts owed by Supplier to the Regents of the University of Michigan pursuant to the terms and conditions of that certain Amended and Restated License Agreement dated October 16, 2007 as amended between Supplier and the Regents of the University of Michigan (the ***"Michigan License"***). During the Term, Supplier hereby covenants that Supplier will: (a) materially comply with all terms and conditions of the Michigan License; (b) not voluntarily terminate the Michigan License or any of Supplier's rights to Supplier's Intellectual Property Rights with respect to the Product thereunder without Distributor's prior written consent or unless Distributor is in breach; and (c) not: (i) amend the Michigan License in any way that would limit or materially modify or restrict Distributor's rights and licenses hereunder or increase or modify Distributor's obligations hereunder, without Distributor's prior written consent; and (ii) waive any of Supplier's rights under the Michigan License in a manner that would materially and adversely affect the rights and licenses granted to Distributor hereunder, without Distributor's prior written consent. Without limiting the generality of the foregoing, Supplier shall not consent or agree (by amendment, waiver, or other action of similar legal effect) to any limitation or narrowing of the scope of Supplier's rights (as they exist on the Effective Date) to Supplier's Intellectual Property Rights under the Michigan License that would materially and adversely affect the rights and licenses granted to Distributor hereunder, without Distributor's prior written consent.

2.6. Marketing and Sales Activities. From the date of Supplier's receipt of HDE Approval for the Product and thereafter for the Term, Distributor shall make such Product available to its sales force and shall use its Commercially Reasonable Efforts to market, promote, distribute and sell such Product in the Territory. Distributor shall be solely responsible for the costs and expenses of establishing and maintaining its sales force and marketing functions for the Product in the Territory, and for conducting its other activities under this Agreement, and shall have the sole authority to control its sales force and direct the activities of its sales force.

2.7. Branding. Supplier shall be solely responsible for the selection (including the creation, searching and clearing), registration, maintenance, policing and enforcement of all trademarks developed for use in connection with the marketing, sale or distribution of the Products (the ***"Product Marks"***). During the Term, Distributor is authorized to use the Product Marks in connection with Distributor's advertisement, promotion and distribution of the Product, and Distributor agrees to submit all intended uses of the Product Marks (other than dissemination of Supplier's promotional materials) to Supplier for prior written approval. Distributor agrees not to attach any additional trademarks, trade names, logos or designations to any Product without prior written consent from Supplier. Distributor further agrees (a) to use the Product Marks solely in the form provided or approved in writing by Supplier and (b) not to use any Product Marks with any product other than the Product. All goodwill arising from use of the Product Marks shall inure to the benefit of Supplier. Distributor agrees that it will not at any time during or after this Agreement assert or claim any interest in or do anything that may adversely affect the validity of any patents, copyrights or trademark belonging to Supplier, including the Product Marks.

3. SUPPLY OF PRODUCTS.

3.1. Forecasting. Distributor shall provide Supplier with a six (6) month non-binding rolling forecast of Distributor's supply requirements for Product (the ***"Rolling Forecast"***) on a monthly basis by the fifth (5^{th}) business day of each calendar month. Distributor may make the Rolling Forecast available for review either (a) online system or (b) by a written report provided by Distributor; provided that, Distributor notifies Supplier where such Rolling Forecast can be found. The Rolling Forecast is provided to Supplier for planning purposes only and does not represent a binding obligation on behalf of Distributor to purchase the quantity of Products set forth therein or for Supplier to provide the quantity of Products set forth therein.

3.2. Inventory and Safety Stock. Supplier shall maintain sufficient quantity of the safety stock at its site(s) in its opinion to ensure continued availability of the Products and uninterrupted service to Distributor. Title and risk of loss to the safety stock remains with Supplier until delivered in accordance with Section 3.6.

3.3. Purchase Orders. Distributor shall notify Supplier of its requirements for quantities of the Products from time to time by submitting a firm Purchase Order to Supplier at least ninety (90) days prior to the requested delivery dates of such Products and Supplier shall be obligated to supply the Products identified in such Purchase Orders confirmed by Supplier after receipt thereof. Any and all such Purchase Orders are subject to this Agreement. Distributor may cancel a Purchase Order issued to Supplier if it provides written notice to Supplier thirty (30) days prior the required delivery date for such Products; provided, however, Distributor may not cancel orders for the Products already shipped to Distributor or otherwise no longer at Supplier's site.

3.4. Delivery, Title and Risk of Loss. Unless otherwise specifically provided for in a Purchase Order, Supplier shall deliver the Products to Distributor's destination specified in the Purchase Order, FOB to 12988 Valley View Road, Eden Prairie, MN 55344.

3.5. Shipment.

3.5.1. *Packaging.* The Products shall be packed and shipped at no additional cost to Distributor in accordance with the Purchase Order and good commercial practice to ensure that no damage shall result during transportation. Supplier represents, to its knowledge, that the articles comprising each shipment or other delivery hereunder made by Supplier to Distributor is, as of the date of such shipment or delivery, in material compliance with all Applicable Requirements and the Specifications.

3.5.2. *Packing Slips.* Supplier agrees to provide a numbered packing slip for the Products delivered to Distributor. At a minimum, Supplier's packing slip will contain the following information: (a) Purchase Order number and (b) the quantity of Products shipped.

3.5.3. *Third Party Manufacturers*. Supplier shall have the right to satisfy its supply obligations under this Agreement either in whole or in part through arrangements with Affiliates or Third Parties engaged by Supplier. If Supplier and Distributor agrees to have Distributor supply a portion or certain components of the Product, the Parties will negotiate a separate agreement in good faith.

3.6. Acceptance and Rejection of Products.

3.6.1. Distributor shall conduct an examination of each shipment of Products promptly after it takes possession and shall have thirty (30) days from delivery of the Products to either: (a) accept the Products; or (b) notify Supplier that it has delivered Non-Conforming Products. Products are ***"Non-Conforming"*** when the particular Product do not meet the requirements set forth in the Specifications at the time of delivery to Distributor, this Agreement, any applicable laws or regulations, or the warranties set forth herein. For the avoidance of doubt, the term ***"Non-Conforming"*** does not include any failure caused directly or indirectly by any failure, act, or omission by Distributor or any of its employees, agents, affiliates, contractors, or vendors, including, but not limited to, failure by Distributor to store and handle Products in accordance with the Product labeling and Specifications. If Distributor fails to accept or notify Supplier within such thirty (30) days, such delivery shall be deemed accepted.

3.6.2. THE SOLE AND EXCLUSIVE REMEDY FOR PRODUCT THAT DOES NOT CONFORM TO THE WARRANTIES SET FORTH IN THIS AGREEMENT OR THE QUALITY AGREEMENT SHALL BE, AT SUPPLIER'S ELECTION, THE REFUND OF THE PRODUCT TRANSFER PRICE FOR SUCH PRODUCT, TOGETHER WITH ANY COSTS OF FREIGHT AND INSURANCE INCURRED IN CONNECTION WITH THE SHIPMENT OF SUCH PRODUCT, OR, THE REPLACEMENT OF SUCH PRODUCT AT SUPPLIER'S COST AND EXPENSE (INCLUDING SHIPPING).

3.6.3. Upon a delivery of any replacement Products, Distributor may then within fifteen (15) days inspect the replacement Products to determine whether Supplier has cured the non-conformity or non-compliance. In the event that Distributor determines that Supplier has failed to correct the Non-Conforming Products, then Distributor shall provide written notice to Supplier and may, subject to Section 3.6.4, in its sole discretion (a) terminate all or a portion of the Purchase Order related thereto, and receive a refund of the applicable charge already paid, if any; (b) deliver to Supplier additional notices of Non-Conforming Products; or (c) avail itself of any other remedies available under applicable law, including, but not limited to termination of this Agreement. If Distributor fails to take any action within such fifteen (15) days, such delivery shall be deemed accepted.

3.6.4. Notwithstanding the provisions of this Section, Distributor shall have the right to revoke its acceptance of any Products, or portion thereof, if Distributor later discovers that Products are Non-Conforming due to latent defects (i.e. a defect that existed as of the date of deliver that causes the Product to be a Non-Conforming Product but such defect is not reasonably discoverable at time of Supplier's delivery of such Products) and promptly provides written notice upon discovery of such latent defect to Supplier, which notice shall describe the latent defect and shall be provided within fifteen (15) days of such discovery.

3.6.5. In the event that the Parties disagree whether a delivered Product is a Non-Conforming Product, the Parties shall appoint a Third Party, which shall be a mutually acceptable independent reputable company with knowledge of similar products in the industry, to review records and perform comparative tests and/or analyses on the Non-Conforming Products. The independent Third Party shall complete and report its findings in writing within thirty (30) days, the findings of which shall be binding on the Parties, absent manifest error. The Parties shall ensure that such independent Third Party is bound to the Parties by obligations of confidentiality no less exacting than those applying between the Parties. Expenses of such independent Third Party shall be borne by the Party whose position is determined to have been in error or, if such independent Third Party cannot place the fault noticed and complained about, then the Parties shall share equally the expenses of such Third Party.

3.7. Quality Assurance Requirements. The Parties will enter into an agreement with respect to quality assurance and/or change control in the supply of the Products including any such quality agreement between the Parties or their Affiliates (the ***"Quality Agreement"***).

4. Pricing, Payment Terms, Royalties and Taxes.

4.1. Upfront Payment. In consideration for the rights and licenses granted herein by Supplier to Distributor, Distributor shall pay Supplier a non-creditable, nonrefundable upfront payment in the amount of [**] due on January 3, 2023. If Supplier does not receive the HDE Approval prior to the first anniversary of the Effective Date, the Supplier (a) shall reimburse to Distributor the [**] previously paid by Distributor to Supplier pursuant to this Section 4.1 and (b) may immediately terminate this Agreement by providing written notice to Distributor.

4.2. Transfer Pricing. Supplier shall sell and supply the Products ordered by Distributor pursuant to Section 3 as set forth on the pricing schedule included on Exhibit C. Pricing under this Agreement shall be deemed Supplier's Confidential Information in accordance with Section 9.

4.3. Trade Price. From and after the Effective Date, Distributor shall have the sole authority to determine the prices of Product sold by or on behalf of it during the Term and to establish its own pricing policy for Product within the Territory, including price increase or decreases and the timing thereof; provided that, (a) on a calendar quarter basis, Distributor shall share with Supplier its then-current pricing policy, including any updates since the last calendar quarter; and (b) if on average in a given calendar year, the price of the Products sold during such calendar year is below the suggested trade price set forth on Exhibit C, Supplier shall have the right to either (i) terminate this Agreement upon written notice to Distributor or (ii) convert the appointment of Distributor from exclusive to a non-exclusive appointment.

4.4. Milestone Payments. In addition to the other payments contemplated by the terms and conditions of this Agreement, Distributor shall pay Supplier the following milestone payments set forth below within 30 days after achievement of the corresponding milestone events. Such payments shall be non-creditable and nonrefundable.

	Milestone Event	Milestone Payment
1.	Supplier's receipt of HDE Approval for the Product from the FDA.	[**]
2.	Sale by or on behalf of Distributor of the first 60 units of Product to any Third Party(ies) other than those institutions set forth on Exhibit E.	[**]

4.5. Royalties; Reports. Subject to this Section 4.5, in addition to the other payments contemplated by the terms and conditions of this Agreement, Distributor shall pay Supplier royalties based on the gross sales of Products in the Territory during the Term at a royalty rate equal to [**]. All royalty amounts payable shall be paid in U.S. dollars within thirty (30) days after the end of the calendar quarter in which the gross sales for the Products were recorded. Each payment of royalties shall be accompanied by a royalty report which shall set forth: (a) the quantity of Products sold in such calendar quarter; (b) the invoiced transfer price for such Products (i.e. the gross sales); (c) the average invoiced transfer price in comparison with the suggested trade price for such calendar quarter, and (c) royalties payable on gross sales. Distributor shall have the responsible to account for and report sales of any Product in the Territory by its sales force and any Permitted Sub-Distributor .

4.6. Records; Audit. Distributor shall keep, and shall cause its Affiliates and Permitted Distributors, to keep complete, true and accurate books of accounts and records sufficient to determine and establish the royalties payable incurred under this Agreement, and compliance with the other terms and conditions of this Agreement. Such books and records shall be kept reasonably accessible and shall be made available for inspection during the Term and for a three (3) year period thereafter. Upon reasonable prior written notice, Distributor shall permit an independent nationally recognized certified public accounting firm, appointed by Supplier and reasonably acceptable to Distributor to inspect the accounts and records of Distributor maintained pursuant to this Agreement to verify the amount of royalties due to Supplier hereunder; provided, that, such inspection shall not occur more often than once per calendar year unless a material error is discovered as part of such inspection, in which case Supplier shall have the right to conduct one more additional thorough inspection for such period. Any inspection conducted under this Section 4.6 shall be at the expense of Supplier, unless such inspection reveals any underpayment of the royalties due hereunder for the audited period by at least [**], in which case the full costs of such inspection for such period shall be borne by Distributor. Any underpayment of the royalties due hereunder shall be paid by Supplier to Distributor within thirty (30) days with interest on the underpayment at the rate specified in Section 4.9 from the date such payment was originally due, and any overpayment of the royalties due hereunder shall be credited against future amounts due by Distributor to Supplier.

4.7. Taxes. Except for taxes expressly set forth in this Agreement, no extra charges of any kind, including without limitation transportation charges, shall be allowed unless agreed to in writing by Distributor and Supplier. Distributor shall pay all sales, or use taxes due on the transactions hereunder or provide Supplier customary proof that the transactions are exempt from such taxes; provided, that Supplier shall pay all applicable excise taxes imposed on Supplier. Invoices shall separately identify any tax that is the responsibility of Distributor hereunder (including value added taxes as exclusively net extra) and shall include either Supplier's sales tax or use tax permit number. Each Party shall pay any taxes arising from such Party's performance of the transactions under the Agreement, including taxes based upon such Party's net income and penalties or fees imposed due to failure to file or pay collected sales or use taxes. In all instances where Distributor purchases the Products using an Incoterm requiring importation by Distributor, Distributor shall have the sole and exclusive right to claim and apply for all duty drawbacks and Supplier shall reasonably assist Distributor in making any such duty drawback claims.

4.8. Invoices. Supplier shall invoice Distributor with Supplier's shipment of the Products with an invoice simultaneously with or within thirty (30) days of delivery which invoice shall include, at a minimum, the following information: (a) Purchase Order number and (b) quantity of the Product(s) shipped. To facilitate prompt payment, all invoices must be directed to, and received by Distributor at the invoice address shown on the applicable Purchase Order.

4.9. Late Payments. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [**] point above the prime rate as published in the Wall Street Journal or any successor thereto, at 12:01 a.m. on the first day of each calendar quarter in which such payments are overdue or (b) the maximum rate permitted by applicable law; in each case calculated on the number of days such payment is delinquent, compounded monthly.

5. Term and Termination.

5.1. Term. Unless earlier terminated in accordance with the provisions of this Agreement, the initial term of this Agreement shall commence on the Effective Date and shall end the three (3) year anniversary of the date that is the earlier of (a) ninety (90) days after Supplier receives the HDE Approval for the Product and (b) the first commercial sale of the Product (the ***"Initial Term"***); *provided however*, that this Agreement shall remain in effect with respect to any Purchase Order then in effect at the time of such termination until performance thereunder is completed, unless or until such Purchase Order is itself terminated as herein provided. This Agreement shall automatically extend for additional terms of one (1) year and for a total of two (2) extensions (each a ***"Renewal Term"***). In the event Distributor elects not to extend, Distributor shall provide written notice to Supplier at least one hundred and eighty (180) days prior to the expiration of the Initial Term or any Renewal Term. The Initial Term of this Agreement and any Renewal Terms are referred to as the ***"Term"*** of this Agreement.

5.2. Termination.

5.2.1. *Termination for Breach.* Either Party may terminate this Agreement upon written notice to the other Party in the event the other Party materially breaches this Agreement and fails to cure the breach within ninety (90) days after receipt of written notice thereof. Material breaches shall include, but are not limited to: (a) the filing of bankruptcy, receivership or similar proceeding due to insolvency (voluntarily or involuntarily); (b) dissolution, liquidation or other discontinuation of all or a significant part of the other Party's business operations or the threat to cease to carry on all or a significant part of it business operations; or (c) any material breach of a Party's obligations under this Agreement, including a material breach of a Party's representations and warranties. Any termination effected pursuant to this Section 5.2.1 shall be deemed effective as of the date specified in the notice of termination if not cured within the ninety (90) day cure period.

5.2.2. *Other Termination*. Supplier may terminate this Agreement pursuant to Sections 4.1, 4.3, or 10.1.2 and either Party may terminate this Agreement pursuant to Section 13.

5.2.3. *Consequences of Termination.* Upon termination of this Agreement, (a) Distributor shall cease commercializing or otherwise selling the Products and shall cease using any Product Marks, (b) all rights granted to Distributor shall terminate, and (c) all of Disclosing Party's Confidential Information shall be destroyed pursuant to Section 9.4 and notice of confirming such destruction shall be provided to Supplier; provided that, if this Agreement is terminated by Distributor pursuant to Section 5.2.1 or is terminated by Supplier pursuant to Section 5.2.2, Distributor may continue to sell Products in its inventory for a period of up to three (3) months following the effective date of the termination subject to the relevant provisions of this Agreement.

5.3. Accrued Obligations. Expiration or termination of this Agreement for any reason shall not release either Party from the obligation to pay any sum that may be owing to the other Party (whether then or thereafter due) or operate to discharge any liability or obligation that had been incurred by either Party prior to any such termination.

5.4. Survival. The following provisions hereof shall survive the expiration or termination of this Agreement and shall be binding to the respective successors, assigns, subsidiaries or Affiliates of the Parties: Sections 4.6, 5.2.3, 5.3, 5.4, 9, 10 and 12.

6. Representations, Warranties and Certain Covenants.

6.1. No Conflict. Supplier represents and warrants to Distributor that as of the Effective Date no Third Party has any right to distribute the Product in the Territory, which right would conflict with the exclusive distribution rights granted to Distributor hereunder. Each Party represents and warrants that the execution and performance by it of its obligations hereunder do not and will not violate or conflict with any obligation that such Party has to any Third Party.

6.2. Compliance with Applicable Requirements. Supplier warrants that the Products manufactured and supplied by Supplier to Distributor shall be manufactured, inspected and supplied substantially in accordance with the Applicable Requirements, and that Supplier's performance hereunder shall otherwise materially comply in all respects with the Applicable Requirements. Distributor represents, warrants and covenants that it shall and shall ensure that the Permitted Sub-Distributor complies with all applicable federal, state, and local laws, statutes, ordinances, regulations, rules, and orders in connection with its performance under this Agreement. Other than FDA authorizations for the Products which shall be the responsibility of Supplier, Distributor shall have sole responsibility to obtain and maintain, at its own expense, all certifications, credentials, authorizations, licenses, and permits necessary in exercising its rights and performing its obligations under this Agreement.

6.3. No Infringement or Misappropriation. Supplier represents and warrants that the Products, including but not limited to the manufacture and supply of the Products by Supplier hereunder and the resale by Distributor and use thereof by customers pursuant to this Agreement, do not violate, infringe, or misappropriate the Intellectual Property Rights or proprietary right of any Third Party in the Territory, nor, to its actual knowledge, has any written claim of such infringement been threatened or asserted.

6.4. Proper Authority. Supplier and Distributor each represent to the other that the execution, delivery and performance of this Agreement by such Party: (a) has been duly authorized by all necessary corporate action; (b) does not conflict with, or result in a material breach of, the articles of incorporation or by-laws of such Party, and any material agreement by which such Party is bound, or any law, regulation, rule, judgment or decree of any governmental instrumentality or court having jurisdiction over such Party; and (c) this Agreement has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party enforceable in accordance with its terms.

6.5. No Pending Claims or Litigation. Each Party represents and warrants to the other Party that there is no action, suit, claim, investigation or proceeding pending or, to the best of its actual knowledge, threatened in writing against it that, if adversely decided, might adversely affect such Party's: (a) ability to enter into this Agreement; or (b) the performance of such Party's obligations hereunder.

6.6. Debarment. Each Party hereby represents and warrants that neither it, nor any Affiliates, agents, subcontractors or employees performing services hereunder are debarred, disqualified, excluded, or otherwise restricted from participating in any government program or procurement process by any governmental body based on operation of local or international law, including participation in clinical development activity, or from any federal or state procurement or health care program pursuant to the regulations of the FDA, its local equivalent, or any other local or international regulatory authority. Each of Supplier and Distributor will notify the other immediately if it learns of any investigation or proceeding that could result in any such restrictions. Upon receipt of notice the receiving party may elect to terminate this Agreement effective as of the date of notice. Any termination by a Party pursuant to this Section 6.6 shall be deemed to be a termination by such for material breach of this Agreement by the other Party.

6.7. No Implied Warranties. THE EXPRESS REPRESENTATIONS AND WARRANTIES GIVEN IN THIS AGREEMENT ARE THE ONLY REPRESENTATIONS AND WARRANTIES GIVEN BY THE PARTIES AND ARE GIVEN IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITH RESPECT TO THE PRODUCT OR ANY COMPONENTS OR OTHER SUPPLIER'S INTELLECTUAL PROPERTY, INFORMATION, MATERIALS OR SERVICES PROVIDED UNDER THIS AGREEMENT. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES GIVEN IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING, TO THE EXTENT APPLICABLE, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OR, TO THE EXTENT APPLICABLE, ANY WARRANTY ARISING FROM COURSE OF DEALING OR TRADE USAGE.

7. Product Labeling and Literature.

7.1. Product Labeling. The Products manufactured by Supplier and sold to Distributor pursuant to this Agreement shall be labeled in accordance with the HDE Approval for such Product by FDA. All Product packages shall contain instructions for use (IFU) in a form that is consistent with the HDE Approval by FDA, which may be updated by Supplier in its sole discretion. Supplier shall be responsible for submitting to the FDA's Global Unique Device Identifier Database (GUDID), maintaining submissions, and ensuring that the device and package label bears the unique device identifier (UDI) through application of Global GS1 standards. For the avoidance of doubt, Supplier shall have sole control and responsibility for ensuring compliance with all legal and regulatory requirements regarding packaging and labeling of the Products provided to Distributor for sales throughout the Territory. Distributor shall not make any changes to any Product packaging or labeling without the prior written consent of Supplier.

7.2. Product Literature. Upon execution of this Agreement, Supplier will provide to Distributor, at Supplier's expense, electronic copies of all existing descriptive materials and sales and technical literature related to the Products for the HDE authorized intended use (the ***"Product Literature"***). Supplier hereby grants to Distributor and its Affiliates and Permitted Sub-Distributors during the Term a non-exclusive, non-transferable, non-royalty bearing limited right and license to access and use the Product Literature, including without limitation, to make and distribute copies thereof and prepare derivative works, marketing materials, images, graphics and related documentation based on the Product Literature, in any media now known or hereafter developed, solely for the purposes to sell, train on, market, promote and distribute the Products as set forth in this Agreement. All derivative works, marketing materials, images, graphics and related documentation based on the Product Literature shall be the property of Supplier and Distributor hereby assigns its rights thereto to Supplier subject to its right to use such works during the Term. Distributor shall obtain Supplier's prior written approval of sales and marketing claims, materials and product literature prior to using and distributing such materials. Distributor shall not use any sales and marketing claims, materials and product literature unless and until Supplier has approved such claims, materials, and literature in writing.

7.3. Support and Training. During the Term of this Agreement, Supplier will keep Distributor reasonably informed of any significant and material new technical developments and information solely relating to the Products that is in Supplier's possession. Supplier agrees to provide to Distributor, at Distributor's expense, the reasonable services of Supplier personnel and such other sales and marketing training and assistance and support, to the extent Supplier reasonably can provide such services, to reasonably enable Distributor's personnel to train its sales force about the Products. Such assistance and support may include, without limitation, to the extent already available, Supplier's provision of data generated to support Product safety and performance, training and education materials. In addition, Supplier agrees to make product experts and other Supplier personnel reasonably available to Distributor from time to time upon Distributor's reasonable request and expense to answer questions in order for Distributor's sales force to make clinician visits and attend marketing collateral for key conferences and the annual and semi-annual Distributor sales meetings.

8. REGULATORY.

8.1. Regulatory Approvals. Supplier shall obtain and/or maintain all legal and regulatory acceptances and approvals that are required for the marketing of the Product in the Territory. Supplier shall comply with any future requirements imposed by the FDA related to its regulatory approvals. Distributor shall provide such assistance from time to time as Supplier reasonably requests in connection with its regulatory compliance. Supplier shall retain exclusive authority and responsibility for all governmental marketing authorizations with respect to the Products in the Territory.

8.2. Permits. Distributor shall obtain and/or maintain all permits, licenses, exemptions, and other authorizations required under the applicable laws and regulations for the distribution of the Products in the Territory and for Distributor's obligations and activities under this Agreement. Distributor shall ensure compliance with the applicable laws and regulations for its Product storage, handling, distribution, marketing, sale, and other activities under this Agreement. Distributor shall comply with the storage, handling, and distribution requirements set forth in the Product labeling and any other Specifications or Product labeling requirements relevant to Distributor's activities.

8.3. Audits. Supplier shall have the right, upon reasonable advanced notice to Distributor, to inspect and audit the facilities being used by Distributor (or any Third Party) for distribution, handling, and storage of the Product to assure compliance by Distributor (and its suppliers' or vendors') with the applicable rules and regulations and the requirements of this Agreement. Distributor shall notify Supplier immediately of FDA, state board, or any other government regulatory notice, communication, inspections or actions relative to Products or Distributor's activities under this Agreement. Distributor shall remedy or cause the remedy of any deficiencies which may be noted in any governmental authority inspection or Supplier audit or present to Supplier a written plan to remedy such deficiencies within ten (10) business days. The failure by Distributor to remedy or cause the remedy of any such deficiencies or to present such a plan and use best efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan shall be deemed a material breach of this Agreement. Distributor acknowledges that the provisions of this Section 8.3 granting Supplier certain audit rights shall in no way relieve Distributor of its obligations under this Agreement, nor shall such provisions require Supplier to conduct any such audits.

8.4. Complaints, Adverse Event Reporting, and Recalls.

8.4.1. Supplier, at its expense, shall be responsible for the prompt review, evaluation and documentation of all complaints relating to the Products. Distributor shall promptly forward to Supplier all complaints received concerning the Products, but in no case later than three (3) days after receipt by Distributor, including all reports of serious injury, product malfunction or other adverse events. Distributor shall cooperate with Supplier's investigation of complaints. Supplier shall comply with the manufacturer requirements under FDA's medical device reporting (MDR) regulations (21 CFR Part 803). Distributor shall maintain complaint files as required for distributors under FDA's MDR regulations (21 CFR Part 803).

8.4.2. Distributor agrees that if Distributor discovers or becomes aware of any fact, condition, circumstance or event (whether actual or potential) concerning or related to the Products which may reasonably require a recall, market withdrawal, correction, or other field action of the Products in the Territory (collectively, a "***Recall***"), that it shall promptly communicate such fact, condition, circumstance or event to Supplier within twenty-four (24) hours. Supplier shall be solely responsible for conducting and shall have the final decision for all Recalls of the Product. Supplier will decide the nature and urgency of any Product Recall. If necessary, Supplier will contact Distributor to coordinate Recall activities. The Parties shall cooperate in giving effect to any necessary Recall. Supplier is solely responsible for any notifications or other communications to FDA or other governmental authorities, and for responding to any inquiries concerning a Product Recall. Distributor shall notify Supplier of any governmental authority inquiries received by Distributor concerning a Product Recall within one (1) day.

8.4.3. Distributor shall refer all written and oral complaints of any kind concerning the Product to Supplier as promptly as possible, but in no event more than 5 business days following Distributor's receipt of such complaint. Distributor shall also provide additional information and documentation as may be reasonably requested by Supplier and available to Distributor. Notwithstanding the foregoing, Distributor may advise the applicable complainant of Distributor's actions with respect to the complaint (i.e., submission thereof to Supplier for resolution). Distributor shall keep a record of all Product-related complaints. Supplier agrees to respond as promptly as possible with the results of its investigation and advise Distributor of the available resolutions of such complaint submitted by Distributor to Supplier under this Section 8.2.3. With respect to all complaints under this Section 8.2.3 each Party agrees to comply with all applicable privacy laws rules and regulations by which the Parties are bound.

8.4.4. Supplier shall bear all costs and expenses and reimburse Distributor for all reasonable out-of-pocket expenses associated with any Recall of the Products, except with regard to any Recall caused in whole or in part by any action, failure, or omission by Distributor or any of its employees, agents, affiliates, contractors, or vendors. Such costs and expenses may include, preparing customer letters, mailing expenses, any other necessary notices, and destruction, return, repair, and/or replacement of the recalled or withdrawn Products, including the cost of shipping and freight.

8.4.5. Distributor shall maintain a system for the traceability of all of the Products shipped from Distributor's stock to end users. The system will, at a minimum, comprise dates, catalogue numbers and lot numbers of each shipment, and such information shall be available at any time upon Supplier's reasonable request and shall comply with the UDI Rule. Such data shall be maintained by Distributor and made available to Supplier upon request for thirteen (13) years, whether or not this Agreement remains in effect.

9. CONFIDENTIAL INFORMATION.

9.1. Confidentiality and Non-use. During the Term of this Agreement and [**] thereafter, the Disclosing Party is willing to disclose Confidential Information to the Receiving Party on the following terms (a) the Receiving Party shall receive, maintain, and hold the Disclosing Party's Confidential Information in strict confidence and will not disclose it to any other person or entity, except to its and its Affiliates' employees, officers, agents, and consultants (the ***"Representatives"***) to whom disclosure is necessary for performance of this Agreement, who have been made aware that the Confidential Information is confidential and are contractually bound to treat it as such; and (b) the Receiving Party and its Representatives shall not utilize any of Disclosing Party's Confidential Information other than for performance hereunder. This Agreement terminates, as of the Effective Date, any confidentiality agreement(s) entered into by the Parties or their Affiliates for the purposes of effectuating this Agreement. All confidential or proprietary information exchanged between the Parties under such prior confidentiality agreement shall be deemed Confidential Information of the corresponding Party under this Agreement and shall be subject to the terms of this Section 9.

9.2. Exceptions. The obligations set forth in Section 9.1 above shall not extend to any portion of Confidential Information: (a) which at the time of disclosure is in the public domain or, after disclosure, becomes part of the public domain, other than as a result of disclosure by the Receiving Party or its Representatives in violation of the terms of this Agreement; (b) that Receiving Party can establish was lawfully in its possession prior to disclosure hereunder; or (c) that is or was received by the Receiving Party from a Third Party having a legal right to transmit the same, free of any confidentiality obligations to the Disclosing Party.

9.3. Authorized Disclosure. Supplier may disclose Confidential Information belonging to Distributor to the extent such disclosure is reasonably necessary in the following situations: (a) filing, prosecuting, defending or enforcing any patent, trademark or other Intellectual Property Right related to the Product, (b) regulatory filings and other filings with governmental authorities (including regulatory authorities), including filings with the FDA, (c) complying with applicable law, including regulations promulgated by securities exchange, and (d) disclosures to any bona fide potential or actual investor, stockholder, investment banker, acquirer, merger partner or other potential or actual financial partner and others on a reasonable need-to-know basis.

9.4. Return or Destruction of Confidential Information. Upon termination or expiration, the Receiving Party shall cease all use and make no further use of any Confidential Information disclosed to it by the other Party and shall, upon written request from the Disclosing Party, promptly return or destroy all of Disclosing Party's Confidential Information (including copies thereof) that is in tangible form (including electronic imaging of Confidential Information) and any documents created by the Receiving Party containing Confidential Information.

9.5. Equitable Relief. The Parties agree that should this Section 9 be breached, money damages would be inadequate to remedy such a breach. As a result, the Disclosing Party shall be entitled to seek, and a court of competent jurisdiction may grant, specific performance, and injunctive or other equitable relief as a remedy for any such breach of this Section 9. Such remedy shall be in addition to all other remedies, including money damages, available to such Party at law or in equity.

9.6. Press Release. The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 9.3 or this Section 9.5. Each Party agrees not to issue any press release or other public announcement disclosing the terms of this Agreement or the transaction contemplated hereby without the prior written consent of the other Party. Notwithstanding the foregoing, the Parties shall agree upon a mutual joint press release to announce the execution of this Agreement, which is attached hereto as Exhibit D; thereafter, Supplier and Distributor may each disclose to Third Parties the information contained in such joint press release without the need for further approval by the other Party. The Parties acknowledge that either or both Parties may be obligated to file under applicable law a copy of this Agreement with the U.S. Securities and Exchange Commission or other governmental authorities. Each Party shall be entitled to make such a required filing, provided, that, it requests confidential treatment of the financial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party.

10. INDEMNIFICATION.

10.1. Supplier Indemnity.

10.1.1. Supplier shall defend, indemnify, and hold harmless Distributor, its Affiliates, and each of its and their officers, directors, employees and other Representatives (***"Distributor Indemnitees"***) from and against any and all Third Party claims, suits and proceedings for any liabilities, claims, suits, actions, losses, costs, expenses (including reasonable attorneys' fees), judgments or damages (***"Losses"***) that are based upon or arise out of (a) infringement, misappropriation, or violation of any Intellectual Property Rights of a Third Party by the use of the Product that was sold by Distributor and used as intended by Supplier; (b) Supplier's negligence or misconduct; (c) material breach by Supplier of a representation, warranty and/or covenant hereunder; (d) violation or failure by Supplier to comply with any federal or state law, regulation, statute, or ordinance including but not limited to the Applicable Requirements and/or Material Declaration Requirements; and (e) failure to comply with the confidentiality obligations set forth herein. The foregoing indemnity obligation shall not apply to the extent that any Loss is subject to indemnity pursuant to Section 10.2.

10.1.2. In the event that Supplier receives a written letter or a filed complaint from a Third Party claiming that it had rights to distribute the Product in the Territory and the Supplier is in breach of the first sentence of Section 6.1, Supplier (a) shall reimburse the amounts previously paid by Distributor to Supplier under this Agreement and (b) may immediately terminate this Agreement by providing written notice to Distributor. THIS REIMBURSEMENT, IN ADDITION TO ANY INDEMNIFICATION OBLIGATION UNDER SECTION 10.1.1 ABOVE, IS THE SOLE AND EXCLUSIVE REMEDY FOR SUPPLIER'S BREACH OF THE FIRST SENTENCE OF SECTION 6.1.

10.2. Distributor Indemnity. Distributor shall defend, indemnify, and hold harmless Supplier, its Affiliates, and each of its and their officers, directors, employees and other Representatives (***"Supplier Indemnitees"***) from and against any and all Third Party claims, suits and proceedings for any Losses that are based upon or arise out of (a) infringement, misappropriation, or violation of any Intellectual Property Rights of a Third Party by any Distributor Indemnitees; (b) Distributor Indemnitee's negligence or misconduct; (c) material breach by Distributor of a representation, warranty and/or covenant hereunder; (d) violation or failure by Distributor to comply with any federal or state law, regulation, statute, or ordinance including but not limited to the Applicable Requirements and/or Material Declaration Requirements; and (e) failure to comply with the confidentiality obligations set forth herein. The foregoing indemnity obligation shall not apply to the extent that any Loss is subject to indemnity pursuant to Section 10.1.

10.3. Indemnification Process. Distributor Indemnitee or Supplier Indemnitee (as applicable, the ***"Indemnitee"***) shall give the other Party from whom indemnity is being sought (the ***"Indemnifying Party"***) prompt written notice of the Third Party claims (provided that any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnitee's rights to indemnification, except to the extent such delay or failure materially prejudices the Indemnifying Party's ability to defend against the relevant claims). The Indemnitee shall reasonably cooperate with the Indemnifying Party. The Indemnifying Party shall have the right to assume the defense (at its own expense) of any such Third Party claim through counsel of its own choosing. The Indemnitee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party. The Indemnifying Party shall not settle or otherwise resolve any such Third Party claim (a) unless such settlement imposes only a monetary obligation on the Indemnitee, which obligation will be indemnified by the Indemnifying Party, or (b) without the prior written consent of the Indemnitee, which such consent shall not to be unreasonably withheld, conditioned or delayed.

10.4. Limitation of Liability. EXCEPT FOR AMOUNTS PAYABLE WITH RESPECT TO THIRD PARTY CLAIMS PURSUANT TO SECTIONS 10.1 AND 10.2 OR DAMAGES ARISING AS A RESULT OF A BREACH OF SECTION 9, OR ARISING FROM A PARTY'S NEGLIGENCE OF WILLFUL MISCONDUCT, IN NO EVENT SHALL SUPPLIER OR DISTRIBUTOR OR THEIR RESPECTIVE AFFILIATES BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES OR LOSS OF USE OR REVENUE, OR PROFITS IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT, ITS TERMINATION, OR ANY BREACH HEREOF.

10.5. Intellectual Property.

10.5.1. *Enforcement of Rights.* If Distributor (a) learns of any infringement or violation by a Third Party in the Territory of any of Supplier's Intellectual Property Rights related to the Product, including any Product Marks, Distributor shall notify Supplier as soon as practicable. Distributor shall have the first right, but not the obligation, at its sole cost and expense to enforce to any infringement or violation in the Territory of Supplier's Intellectual Property Rights solely related to the Product. Distributor shall give Supplier a reasonable opportunity to review and comment on the text of any filing or submissions to be made by Distributor in connection with any such action. Supplier shall have the right to be represented by counsel of its own choice, at its own cost and expense. If Distributor elects not to initiate, or intends to cease an action to terminate to enforce such Supplier's Intellectual Property Rights, Distributor shall give prompt notice to Supplier and Supplier shall have the right (but not the obligation) to initiate or continue such action. If Supplier elects to initiate or continue such action, then Distributor shall execute such documents and perform such acts as may be reasonably necessary to effect a transfer of such responsibility to Supplier in a timely manner to allow the Supplier to initiate or continue such action.

10.5.2. *Defense of Infringement Claims.* If any Third Party asserts a claim against Distributor (or any of its Affiliates or Permitted Sub-Distributors) alleging that the Product infringes, misappropriates or violates the Intellectual Property Rights of any Third Party (any such claim being referred to as an ***"Infringement Claim"***), the Party first having notice of the Infringement Claim shall promptly notify the other Party thereof in writing specifying the facts, to the extent known, in reasonable detail. Distributor shall have the first right, but not the obligation, at its sole cost and expense to defend to any Infringement Claim. Distributor shall give Supplier a reasonable opportunity to review and comment on the text of any filing or submissions to be made by Distributor in connection with any such action. Supplier shall have the right to be represented by counsel of its own choice, at its own cost and expense. If Distributor elects not to initiate, or intends to cease an action to terminate to defense of such Infringement Claim, Distributor shall give prompt notice to Supplier and Supplier shall have the right (but not the obligation) to initiate or continue such action. If Supplier elects to initiate or continue such action, then Distributor shall execute such documents and perform such acts as may be reasonably necessary to effect a transfer of such responsibility to Supplier in a timely manner to allow the Supplier to initiate or continue such action.

10.5.3. *Cooperation*. To the extent that any infringement or violation by a Third Party or an Infringement Claim covers (a) Intellectual Property Rights in the Territory and outside the Territory and/or (b) Products and other products not covered by this Agreement, Distributor shall cooperate in good faith with Supplier and Supplier's other distributors in good faith in connection with any enforcement and defense strategy.

10.5.4. *Ownership*. As between the Parties, all Intellectual Property Rights related to the Products shall be owned by Supplier. Distributor shall not decompile, disassemble or reverse engineer any Products or components thereof and shall not file any patent applications based on any inventions arising from the breach of this Section 10.5.4.

11. INSURANCE. The Parties shall maintain adequate insurance, including but not limited to product liability insurance, in such amounts and with such insurance companies as is customary in accordance with sound business practices consistent with the nature of the Product and the responsibilities of the Parties under this Agreement. Upon termination of this Agreement for any reason, each Party shall maintain such insurance in full force and effect (or "tail" coverage shall be obtained) for a period of two (2) years following such termination.

12. INDEPENDENT CONTRACTOR.

12.1. Relationship of the Parties. Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. Nothing in this Agreement shall be construed to give either Party the right or power to direct or control the activities of the other Party or to authorize either Party to bind the other Party to, or assume or create any contract and obligation of any kind, express or implied, on behalf of the other Party or to any other person.

12.2. No Right to Participate in Distributor Plans. No amounts payable by Distributor under this Agreement will be considered salary for pension and incentive compensation purposes. Furthermore, because Supplier is engaged in its own independent business, Supplier and Supplier's employees, suppliers, subcontractors, agents, or representatives are not eligible for and will not participate in Distributor's retirement plans, insurance plans, and any other benefits normally afforded to employees of Distributor. Supplier agrees to pay, and hereby accepts full and exclusive liability for the payment of, any and all contributions and taxes for Unemployment Compensation or Disability Insurance or Old Age Pension or Annuities, and all similar provisions now or hereafter imposed by any federal or state governmental authority, which are imposed with respect to or measured by wages, salaries, or other compensation paid by Supplier to persons employed or retained by Supplier.

12.3. Assignment. Except as otherwise set forth herein, neither party may assign this Agreement, in whole or in part, without the prior written consent of the other Party (which consent shall not be unreasonably withheld). This Agreement shall inure to the benefit of and be binding upon each Party signatory hereto, their respective successors, and permitted assigns. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement. Any attempted assignment of this Agreement not in compliance with this Section 12.3 shall be null, void, invalid and of no force or effect ab initio.

13. Force Majeure. In the event that either Party is unable to perform any of its obligations under the Agreement, or to enjoy any of its benefits because of fire, natural disaster, action or decrees of governmental bodies wholly beyond the control of a Party causing its inability to perform (a ***"Force Majeure Event"***), the Party who has been so affected shall immediately give written notice to the other Party and shall use Commercially Reasonable Efforts to resume performance. If the period of nonperformance exceeds thirty (30) days from the receipt of notice of the Force Majeure Event, the Party whose ability to perform has not been so affected may by giving written notice terminate the Agreement. Delays in delivery due to Force Majeure Events shall automatically extend the delivery date for a period equal to the duration of such Force Majeure Events. Any acceptance or warranty period affected by a Force Majeure Event shall likewise be extended for a period equal to the duration of such Force Majeure Event. As applied to this Section 13 and to determine whether an event is wholly beyond control of a Party, the following are not Force Majeure Events: (i) strikes, slowdowns, or other labor related delays, or (ii) any event resulting from any act or omission of the affected Party. A period of Force Majeure or other event causing inability to perform shall be deemed to commence on the date that the event of Force Majeure or other such event first occurs. The payment of invoices due and owing hereunder shall in no event be delayed by the paying Party because of a Force Majeure Event.

14. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware as applicable to contracts made and to be performed in that state, without regard to conflicts of laws principles, suit to enforce the interpretation or application of this Agreement shall be brought within a court of competent jurisdiction, state or federal, located within the State of Delaware. The Parties expressly disclaim application of or reference to the United Nations Convention on Contracts for the International Sale of Goods.

15. Compliance with Laws. The Parties are an equal opportunity employer and federal contractor. Consequently, the Parties agree that, to the extent applicable to its performance hereunder, each Party shall comply with all applicable federal, state, and local laws, rules and regulations, including without limitation the laws, rules and regulations referred to in this Agreement and the following, which are incorporated herein by reference, as applicable: (a) the Jobs for Veterans Act (38 U.S.C. §§ 4211-4212); (b) Section 503 of the Rehabilitation Act of 1973 (29 U.S.C. § 793); (c) the Office of Federal Contract Compliance Programs' implementing regulations (41 CFR 60-1.4(a), 41 CFR 60-300.5(a) and 41 CFR 60-741.5(a)); (d) Executive Order 11246; and (e) Executive Order 13496 (29 CFR Part 471, Appendix A to Subpart A), relating to the notice of employee rights under federal labor laws, specifically: **each Party and its subcontractors (or Permitted Sub-Distributors) for this Agreement shall abide by the requirements of 41 CFR 60-300.5(a), as applicable. This regulation prohibits discrimination against qualified protected veterans, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans. Each Party and its subcontractors (or Permitted Sub-Distributors) for this Agreement shall abide by the requirements of 41 CFR 60-741.5(a), as applicable. This regulation prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified individuals with disabilities.** Each Party further agrees that it shall comply with the requirements of Sections 6, 7, and 12 of the Fair Labor Standards Act, as amended, and all regulations and orders issued under Section 14 thereof. The laws, rules, and regulations set forth in this Section 15 are in addition to all other laws, rules, and regulations contained in this Agreement as requirements and are incorporated herein by this reference.

16. Country of Origin. Supplier shall maintain and provide copies to Distributor of a listing accurately specifying the country of origin of each of the Products to be supplied under this Agreement. For purposes of this Section 16, the term "country of origin" shall be interpreted consistent with the "substantial transformation test" (i.e., transforming an article into a new and different article of commerce, with a name, character, or use distinct from the original article).

17. Tooling and Equipment. Equipment, design, tools, jigs, dies, fixtures, templates, patterns, drawings, and other information and things (herein collectively, the ***"Tools"***) paid for or furnished by Distributor and does not contain any of Supplier's Confidential Information or Intellectual Property Rights shall be Distributor's property and Supplier shall not encumber or dispose of them in any way. Distributor shall maintain the Tools in good working condition.

18. Dispute Resolution. The Parties shall use reasonable efforts to resolve any dispute relating to this Agreement through a meeting of appropriate managers for each Party. If the Parties are unable to resolve the dispute, either Party may escalate the dispute to its executives. If an executive level meeting fails to resolve the dispute within thirty (30) days after escalation, either Party may seek any available legal relief. This provision shall not affect either Party's right to seek injunctive or other equitable relief at any time.

19. Notices. Any notice required or permitted hereunder shall be given in writing and delivered (a) personally, (b) by express courier, or (c) by electronic mail, followed by registered or certified mail, return receipt requested, postage prepaid, to the Party entitled thereto at the following address for each such Party:

To Distributor:	Nuwellis, Inc. 12988 Valley View Road Eden Prairie, Minnesota 55344 Attention: Nestor Jaramillo, Jr., CEO & President Neil P. Ayotte, SVP & GC Email: [**]; [**]
with a copy (which shall not constitute notice) to:	Honigman LLP 660 Woodward Avenue Detroit, Michigan 48226-3506 Attention: Jessica Herron, Esq. & Phillip D. Torrence, Esq. Email: [**]; [**]
To Supplier:	SeaStar Medical Holding Corporation 3513 Brighton Blvd, Suite 410 Denver, Colorado 80216 Attention: Eric Schlorff, CEO Email: [**]
with a copy (which shall not constitute notice) to:	Morgan, Lewis & Bockius LLP 1400 Page Mill Road Palo Alto, California 94304 Attention: Albert Lung, Esq. Email: [**]

Either Party may change such address by giving notice to the other of such change in the manner contemplated by this Section 19. The return receipt, the delivery receipt, electronic confirmation of receipt, or the affidavit of messenger will be deemed conclusive but not exclusive evidence of delivery; delivery will also be presumed at such time as delivery is refused by the addressee upon presentation.

20. MISCELLANEOUS.

20.1. Remedies. No remedy herein conferred is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to every other remedy given hereunder or now or hereafter existing at law or in equity or by statute or otherwise.

20.2. Counterparts/Electronic Execution and Delivery. This Agreement may be executed in one or more counterparts and by facsimile or electronic delivery, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

20.3. Waiver; Modification of Agreement. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party's rights to the subsequent enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time executed by an authorized officer of the waiving Party. No subsequent alteration, amendment, modification, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

20.4. Headings. The headings in this Agreement are for convenience of reference only and in no way define or limit any of the provisions hereof or otherwise affect their construction or effect.

20.5. Severability. In case any one or more of the provisions of this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

20.6. Exhibits. The Exhibits described below and attached hereto are incorporated into this Agreement wherever referenced.

EXHIBIT A	Definitions
EXHIBIT B	Permitted Subcontractors
EXHIBIT C	Transfer Pricing and Suggested Trade Price
Exhibit D	Joint Press Release

20.7. Entire Agreement. This Agreement, including any documents referred to herein and any exhibits attached hereto, are incorporated herein by reference and constitute the entire agreement between the Parties with respect to the subject matter hereof, and there are no other representations, warranties, covenants, or obligations except as set forth in this Agreement and the signing by both Parties shall cause this Agreement to be valid on the Effective Date. This Agreement supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions, written or oral, of the Parties, relating to any transaction contemplated by this Agreement (including any confidentiality agreement(s) entered into by the Parties or their Affiliates for the purposes of effectuating this Agreement). No course of dealing or usage of trade shall be used to modify the terms hereof. This Agreement is the product of negotiations between the Parties, and shall be construed as if jointly prepared and drafted by them, and no provision hereof shall be construed for or against any Party due to its actual role in the preparation or drafting hereof by reason of ambiguity in language and/or rules of construction against the drafting Party or similar doctrine. The documents referred to herein and attached hereto shall be read together with this Agreement to determine the Parties' intent. In the event of a conflict between or among such documents, this Agreement shall govern.

SIGNATURES ON THE FOLLOWING PAGE

In Witness Whereof, the Parties hereto have caused this Agreement to be executed by their duly authorized corporate officers or representatives as of the date first above written.

DISTRIBUTOR:

Nuwellis, Inc.

By: /s/ Nestor Jaramillo, Jr.
Name: Nestor Jaramillo, Jr.
Title: President & CEO

SUPPLIER:

SeaStar Medical Holding Corporation

By: /s/ Eric Schlorff
Name: Eric Schlorff
Title: Chief Executive Officer

Signature Page to
License and Distribution Agreement

EXHIBIT A

DEFINITIONS

"***Affiliates***" means (a) any corporation or business entity where fifty percent (50%) or more of the voting stock is, and continues to be, owned directly or indirectly by any Party hereto; (b) any corporation or business entity that directly or indirectly owns fifty percent (50%) or more of the voting stock of any Party hereto; (c) any corporation or business entity under the direct or indirect control of such corporation or business entity as described in (a) or (b); or (d) in the case of Distributor, any corporation or business entity that satisfies the criteria set forth in (a), (b) or (c) at any time during the Term of this Agreement.

"Agreement" shall have the meaning set forth in the Preamble.

"***AKI***" shall have the meaning set forth in the Recitals.

"Applicable Requirements" means all applicable domestic and foreign federal, state, and local laws, statutes, acts, ordinances, rules, codes, standards, guidelines and regulations, applicable to the Supplier and/or the Products provided under this Agreement. Without limiting the generality of the foregoing, "Applicable Requirements" means all rules and regulations applicable to the labeling, re-labeling, packaging, processing, assembly, record creation, record retention, record modification, record transmission (including by electronic means), storage, handling, transport (including exportation and importation of Products within the United States, or to or from the United States and any other country), and reporting of medical devices, and, as applicable, human cells, tissues or human cellular or tissue-based products (HCT/Ps, in accordance with 21 CFR 1271) in effect at a particular time and promulgated by the United States Food and Drug Administration (***"FDA"***) and any foreign agency or authority equivalent to the FDA, including without limitation 21 CFR 820 (the ***"Quality System Regulation"***) and, 21 CFR 11 (Electronic Records Regulation), if applicable.

"Commercially Reasonable Efforts" means with respect to the activities of a Party, those efforts and resources, including the use of reasonably necessary personnel, equivalent to the efforts that a reasonable distributor or supplier, as applicable, of medical device in the United States, in each case, that is of comparable size and has comparable resources to such Party would typically devote to a product that is of similar market potential, profit potential, and strategic value.

"Confidential Information" means: (a) the terms of this Agreement, including any information shared during negotiation of this Agreement; and (b) all information disclosed by or on behalf of a Party (the ***"Disclosing Party"***) to the other Party (the ***"Receiving Party"***), whether tangible or intangible, which (i) is marked as confidential (or the like), (ii) is designated by the Disclosing Party to be confidential at the time of disclosure, or (iii) should be known or understood to be confidential by a person exercising reasonable commercial judgment in the circumstances, whether or not marked, designated or confirmed as confidential by the Disclosing Party, including without limitation any information related to or regarding the Disclosing Party's business plans, methodologies, strategies, product specifications, development plans, manufacturing data, pricing, quantity requirements, and any technical, marketing, financial, customer, supplier, and employee information including plans, drawings, or samples.

"Control" means, with respect to Intellectual Property Rights, possession by a Party, whether by ownership or license (other than pursuant to this Agreement), of the ability to grant a license or sublicense as provided in this Agreement without violating the terms of any written agreement with any Third Party.

"***CRRT***" shall have the meaning set forth in the Recitals.

"Distributor" shall have the meaning set forth in the Preamble.

"Effective Date" shall have the meaning set forth in the Preamble.

"Force Majeure Event" shall have the meaning set forth in Section 13.

"***HDE***" shall have the meaning set forth in the Recitals.

"HDE Approval" means receipt by Supplier from FDA of a written authorization to market the Product for pediatric use with weight limit of 20 kgs and authorized selling units of at least 4,000 units pursuant to the submitted HDE application around July 20, 2022, as amended between date of submission and issuance of the authorization letter.

"***Infringement Claim***" shall have the meaning set forth in Section 10.3.2.

"Initial Term" shall have the meaning set forth in Section 5.1.

"Intellectual Property Rights" means domain names, company names, registered or unregistered trademarks, trade names, logos, service marks, trade dress rights, trade secret rights, registered and unregistered designs, moral rights, patents, patent rights and any applications for registration thereof, and any know how, concepts, ideas, discoveries, inventions (whether or not patentable), processes, developments, suggestions, materials, improvements, works of authorship, artwork, software, documentation, copyrights and database rights, intellectual property, rights in other tangible and intangible assets of a proprietary nature, and the like as may exist now and/or hereafter come into existence and all renewals and extensions thereof, under the laws of the United States or any other state, country or jurisdiction.

"Michigan License" shall have the meaning set forth in Section 2.5.

"Negotiation Notice" shall have the meaning set forth in Section 2.3.

"Negotiation Period" shall have the meaning set forth in Section 2.3.

"New Products" shall have the meaning set forth in Section 2.3.

"Non-Conforming Products" shall have the meaning set forth in Section 3.7.1.

"Other Authorized Uses" means investigational uses requested by SeaStar in writing that are either approved by or exempt from FDA requirements.

"Party" and ***"Parties"*** shall have the meaning set forth in the Preamble.

"Permitted Sub-Distributor" shall have the meaning set forth in Section 2.2.

"Product" means the SCD currently being developed by Supplier as of the Effective Date for the treatment of pediatric patients with AKI on CRRT pursuant to the HDE authorization and any modified, enhanced or supplemented (i.e. components of the existing Product are supplemented) version of the existing SCD.

"Product Literature" shall have the meaning set forth in Section 7.2.

"Product Marks" shall have the meaning set forth in Section 2.7.

"Purchase Order(s)" shall mean a binding document (in hard copy or electronic form) that Distributor may, from time to time, issue to Supplier after the Effective Date of this Agreement in order to purchase Products. Each Purchase Order shall specify the a number for the purchase order, date of delivery, and the amount of the Products to be delivered to Distributor's facility.

"Quality Agreement" shall have the meaning set forth in Section 3.7.

"Recall" shall have the meaning set forth in Section 8.4.2.

"Renewal Term" shall have the meaning set forth in Section 5.1.

"Representatives" shall have the meaning set forth in Section 9.1.

"Rolling Forecast" shall have the meaning set forth in Section 3.2.

"***SCD***" shall have the meaning set forth in the Recitals.

"Specifications" shall have the meaning set forth in the Quality Agreement.

"Supplier" shall have the meaning set forth in the Preamble.

"Term" shall have the meaning set forth in Section 5.1.

"Third Party" shall mean any individual or entity other than a Party or an Affiliate of a Party.

"Territory" shall mean the United States of America.

"Tools" shall have the meaning set forth in Section 17.

EXHIBIT B

PERMITTED SUBDISTRIBUTORS

- [**]

EXHIBIT C

Transfer Pricing and Suggested Trade Price

Product Name	Transfer Price (per unit)
The SCD currently being developed by Supplier as of the Effective Date for the treatment of pediatric patients with AKI on CRRT	[**]

Suggested Trade Price: [**] per unit. On a quarterly basis, this suggested trade price will be reviewed and evaluated for market acceptance by both parties.

EXHIBIT D

Joint Press Release

EXHIBIT E

Excluded Institutions Solely for the Purposes of Achievement of the Second Milestone in Section 4.4

- [**]
- [**]
- [**]
- [**]
- [**]

EXHIBIT 21

SUBSIDIARIES

Entity	Jurisdiction of Formation
Sunshine Heart Ireland Limited	Ireland
CHF Solutions, LLC	Delaware (Dissolved in February 2022)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-215112, 333-216053, 333-216841, 333-221010, 333-221716, 333-229102, 333-235658, 333-235385, 333-236050, 333-237911, 333-238811, 333-230142 and 333-241454, and 333-267368, Form S-3 (File No. 333-256797), and Form S-8 (File No. 333-183924, 333-183925, 333-188935, 333-190499, 333-194642, 333-202904, 333-210215, 333-218464, 333-223879, 333-233152, 333-238276, 333-254708, 333-256432 and 333-264417) of Nuwellis, Inc. of our report dated March 3, 2023, relating to the consolidated financial statements for the year ended December 31, 2022, appearing herein, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern.

/s/ Baker Tilly US, LLP
Minneapolis, Minnesota
March 3, 2023

EXHIBIT 31.1

NUWELLIS, INC.
CEO SECTION 302 CERTIFICATION

I, Nestor Jaramillo Jr, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Nuwellis, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2023

/S/ NESTOR JARAMILLO JR
Nestor Jaramillo Jr
Chief Executive Officer

EXHIBIT 31.2

NUWELLIS, INC.
CFO SECTION 302 CERTIFICATION

I, Lynn Blake, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Nuwellis, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2023

/S/ LYNN BLAKE
Lynn Blake
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Nuwellis, Inc. (the ***"Company"***) on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, Nestor Jaramillo, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 3, 2023

/S/ NESTOR JARAMILLO JR

Nestor Jaramillo Jr
Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Nuwellis, Inc. (the ***"Company"***) on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, George Montague, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 3, 2023

/S/ LYNN BLAKE

Lynn Blake
Chief Financial Officer