nuwellis®
Restoring Fluid Balance. Transforming Care.®

Dear Nuwellis Stockholders: May 17, 2024

2023 proved to be a year of significant progress for Nuwellis. We navigated a challenging environment for micro-cap companies while staying focused on our strategic growth initiatives, including new product development, expanding our clinical and market access to the Aquadex® system in treating heart failure patients, and enhancing our strategic collaborations with key strategic partners. This resulted in a strong second half, with overall revenue growth of 27% compared to the first half of the year.

A key highlight was the remarkable turnaround in domestic console sales, surging 207% in the second half of the year. This signifies strong potential for future utilization and patient treatment with the Aquadex system for patients suffering from fluid overload. We ended 2023 with record fourth quarter revenue, demonstrating continued momentum.

We remain committed to our internal product development. We continue to advance the pediatric continuous kidney replacement therapy device, Vivian™. We, along with many pediatric nephrologists, believe this product holds the promise to significantly improve the survival and quality of life in neonates born with kidney disfunction. Additionally, the late-2023 FDA clearance for the 11cm dELC Catheter provides physicians with more venous access options for adult treatments using the Aquadex system.

In 2023, we solidified our corporate development efforts with a strategic collaboration with DaVita. This collaboration allows us to pilot Aquadex therapy for adult heart failure patients in select U.S. markets. Pairing Aquadex with DaVita's clinical infrastructure could potentially help accelerate the clinical adoption of ultrafiltration when first-line medical treatments are ineffective. Our organization is thrilled and actively collaborating with the DaVita team as we prepare to begin patient therapy.

We are also pleased with the progress of our distribution partner, SeaStar Medical. Their Selective Cytopheretic Device (SCD), Quelimmune™, received FDA HDE approval in February 2024. With exclusive U.S. license and distribution rights, we have begun commercializing Quelimmune in targeted medical centers. The unique technology behind Quelimmune has demonstrated a 77% survival rate in children with potentially deadly hyperinflammation. This product complements Vivian, further strengthening our pediatric care portfolio.

Since Aquadex' s commercial reintroduction in 2016, we have positively impacted the lives of approximately 25,700 patients and their families. The milestones achieved in 2023 and our plans for 2024 bring us closer to our ambitious goal of treating 100,000 patients within ten years. We commend our dedicated employees, whose resilience, passion, and tenacity continue to drive Nuwellis' mission forward.

With the momentum gained in the latter half of 2023, increased awareness of Aquadex' s efficacy, and the valuable milestones achieved, despite capital market headwinds, we believe that Nuwellis is poised for meaningful growth in 2024. We remain excited about the future and are committed to delivering value to our investors, customers, and the patients we serve.

Thank you for your continued support, without it, we would not be able to achieve key advances in transforming the lives of patients suffering from fluid overload.

Very truly yours,

Nestor Jaramillo, Jr.
President & Chief Executive Officer

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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, 2023

☐ **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, 2023, 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, 2023 closing sale price of $2.69 per share) was approximately $5.0 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of March 1, 2024 was 6,801,443 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2024 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.[1]

The signs and symptoms of fluid overload are not always the same in each patient and may vary. However, possible signs and symptoms of fluid overload include pulmonary edema/pleural effusion, peripheral edema, anasarca (swelling of the skin) ascites, jugular vein distention and dyspnea.[2] Medical conditions or diseases where excess fluid accumulates in the body are heart failure, kidney failure, nephrotic syndrome, cirrhosis, or burn injuries/trauma. Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery, although fluid overload is the leading cause of death for critically ill patients in the ICU within 90 days of admission.[3] The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight, presence of pulmonary rales, and edema), blood chemistry, natriuretic peptides, liver enzymes, hemoglobin and hematocrit, blood volume analysis, and/or bioimpedance analysis.[4] Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema[5] and is a leading cause of hospital readmissions with patients suffering from heart failure and patients following cardiac surgery.[6]

The condition of fluid overload is often observed in patients with heart failure and secondary oliguric states,[7] although in pediatric patients, fluid overload is associated with significant increases in mortality.[8, 9] Congestion or fluid overload, the hallmark of decompensated heart failure or HF, is the primary reason for hospitalization in 90% of these patients.[10, 11] For this reason, diuretics have been the cornerstone of heart failure treatment for more than 50 years.[12] Over the past 20 years, approaches to treatment have changed dramatically.[13]

1 Murugan R et al. Nature Rev Nephrol. 2020; 1-14.
2 Koratala A et al. Cardiorenal Med. 2022;12(4):141-154.
3 Vaara ST et al. *Crit Care*.2012; 16: 1-11.
4 Koratala A et al Cardiorenal Med. 2022;12(4):141-154
5 Stein, A, et. al. Critical Care, 2012:16:R99.
6 Iribarne A, et al. Ann Thorac Surg. 2014; 98(4): 1274-80.
7 Ronco C, Costanzo MR, Bellomo R, et al. (2010) Fluid Overload Diagnosis and Management. Basel, Switzerland: Karger.
8 Sutherland SM, et al. *Am J Kidney Disease*. 2010; 5(2): 316-25.
9 Gillespie RS, et al. *Ped Nephro*. 2004; 19(12): 1394-99.
10 Kazory A & Costanzo MR. *Adv Chronic Kidney Dis*. 2018; 25(5): 434-442.
11 Fonarow GC. Rev Cardiovasc Med. 2003; 4: s21-30.
12 Kamath SA. *Int J of Nephrol*. 2011; 1-6.
13 Ellison DH. *Cardio*.2001;96:132-143

These dramatic improvements include new medications and new technologies, such as ultrafiltration, to help treat fluid overload. Each year there are over 1 million heart failure hospitalizations in the United States, and 90% of those hospitalizations are due to symptoms of fluid overload.[14] These patients are hospitalized on average for 8.3 days at a cost of approximately $24,000[15], to which reimbursement will only cover about 34%[16] of that cost. On top of that, there is a 30-day readmission penalty for which the hospitals absorb another cost but do not get reimbursed with some data suggesting such penalties can cost a hospital up to $15.2 million annually.[17, 18, 19]

Treatments for Fluid Overload

Diuretics

Treatment for fluid overload has traditionally been achieved through use of oral or loop diuretics which may be accompanied by use of other categories of medications, such as angiotensin-converting enzyme (ACE) inhibitors, sodium-glucose co-transporter 2 (SGLT-2) inhibitors, Aldosterone receptor antagonists (MRAs), beta-blockers, and inotropic drugs. Chronic diuretic use has been associated with increased long-term mortality and hospitalizations in a wide spectrum of chronic systolic and diastolic HF patients.[20] Increasing concern exists that diuretics, particularly at high doses, may be deleterious in the inpatient setting. Diuretics have a variable dose response rate and studies have shown nearly 70% of heart failure patients treated with diuretics have a suboptimal response.[21, 22] Additionally, between 10-40% of heart failure and cardiac surgery patients are refractory to diuretics,[23] with diuretic resistance associated with a higher risk of in-hospital worsening of heart failure, increase mortality after discharge, and a 3-fold increase in rehospitalization rates.[24] In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.[25] Also, long term use of diuretics has been associated with kidney damage.[26] Approximately 40% of heart failure patients have poor diuretic response.[27] This poor response is possibly due to noncompliance or high intake of salt, poor drug absorption, insufficient kidney response to drug, and reduced diuretic secretion.[28] Despite treatment with loop diuretics, patients are frequently hospitalized and treated for recurrent symptoms and signs of fluid overload. Among more than 50,000 patients enrolled in the Acute Decompensated Heart Failure National Registry ("ADHERE") study, only 33% lost ≥ 2.27 kg (5 lbs.), and 16% gained weight during hospitalization.[29]

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[30] Additionally, one study found that 24% of such patients were readmitted to the hospital within 30 days of their discharge, and up to 42-50% were readmitted at 90 days and 6 months respectively.[31, 32] Regardless of diuretic strategy, 42% of acutely decompensated heart failure subjects in the DOSE (Diuretic Optimization Strategies Evaluation) trial reached the composite endpoint of death, rehospitalization, or emergency department visit at 60 days.[33] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[34] Therefore, an alternative therapy to help stabilize or improve patient care is needed.

14 Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445.
15 From Premier Applied Sciences database.
16 Reimbursement estimates from MCRA.
17 Costanzo MR, et al. *J Am Coll Cardiol*. 2017;69(19):2428-2445.
18 McIlvennan CK, Eapen ZJ, Allen LA. *Circulation*. 2015 May 19;131(20):1796-803.
19 From Premier Applied Sciences database.
20 Ahmed A, et al. *Eur Heart J.* 2006 Jun;27(12):1431-9.
21 Kazory A & Costanzo MR. *Adv Chronic Kidney Dis*. 2018; 25(5): 434-442; 30.
22 Testani JM, Hanberg JS, Cheng S et al. *Circ Heart Fail*. 2016; 9(1): e002370.
23 Testani JM, Hanberg JS, Cheng S et al. *Circ Heart Fail*. 2016; 9(1): e002370.
24 Costanzo MR, et al. *J Am Coll Cardiol*. 2017;69(19):2428-2445.
25 Kamath SA. *Int J of Nephrol*. 2011: 1-6.
26 Felker MG & Mentz RJ. *J Am Coll Cardiol*. 2012;59(24):2145-53.
27 Testani JM. *Circ Heart Fail*. 2016 Jan;9(1):e002370.
28 Hoorn EJ & Ellison DH. *Am J Kidney Dis*. 2017;69(1):136-142.
29 Gheorghiade M, et al. *Eur Heart J Suppl*. 2005; 7:B13– 19.
30 Orso D, et al. *Eur Rev Med Pharmacol Sci*. 2021 Apr;25(7):2971-2980.
31 Costanzo MR, et al. *J Am Coll Cardiol*. 2017;69(19):2428- 2445.
32 Thandra A, et al. *Clin Invest*. 2023; 365(2): 145-51.
33 Felker GM, et al. *N Engl J Med*. 2011; 364:797–805.
34 Costanzo MR, et al. *J Am Coll Cardiol*. 2007; 49(6):675-683.

Ultrafiltration.

Ultrafiltration, or aquapheresis, is an alternative therapy to diuretics for fluid removal in patients with volume overload. Ultrafiltration has been a well-documented technique in the treatment of fluid overload in heart failure patients for over 20 years.[35] Ultrafiltration is a safe and effective therapy to treat fluid overload and congestion by removing the overload of fluid and congestion by removing extra fluid and salt.[36] With ultrafiltration, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The use of ultrafiltration therapy in subgroups of patients, such as heart failure and post-cardiac surgery, has demonstrated clinical benefits in treating fluid overload signs and symptoms. In addition to the clinical benefits of ultrafiltration, the therapy provides economic advantages. One hospital cost analysis demonstrated a total cost savings of $3,975, or 14.4%, per patient when using ultrafiltration as compared to diuretic therapy over 90 days.[37]

The Aquadex System

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

With the Aquadex System, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The Aquadex System has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate.[38, 39] Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex System may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies. The Company estimates it has treated nearly 26,000 patients across all three (3) of our customer categories, since it reintroduced the Aquadex System to the U.S. market in 2016.

Benefits of the Aquadex System

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

- Reduces hospitalization by 81%[40] compared to diuretics;
- Rehospitalizations with Aquadex were 48% lower than the national average at 30 days;[41]
- Reduces length of hospital stay when initiated early, resulting in average savings of $3,975 (14%);[42]
- Stabilizes or improves cardiac hemodynamics;[43, 44]
- Safe, easy-to-use, and flexible in application;
- Provides complete control over rate and total volume of fluid removed by allowing a medical practitioner to specify the amount of fluid to be removed from each individual patient;
- Can be performed via peripheral or central venous access;
- Predictably removes excess isotonic fluid (extracts water and sodium while sparing potassium and magnesium; decrease risk of electrolyte abnormalities);[45, 46]

35 Agostoni PG, et al. *J Am Coll Cardiol*. 1993; 21(2):424-431.
36 Kazory A, et al. *Cardiorenal Med*. 2023;13(1)1-8.
37 Costanza MR, et. al. *Value Health*. 2018; 21 (Suppl 1):S167.
38 SAFE Trial: Jaski BE, et al. J Card Fail. 2003; 9(3): 227-231.
39 RAPID Trial: Bart BA, et al. *J Am Coll Cardiol*. 2005; 46(11): 2043-2046.
40 Watson R et al. *Am Heart J Plus: Cardiol: Res & Pract. 2022; 242:1-6*.
41 Watson R et al. *Am Heart J Plus: Cardiol: Res & Pract. 2022; 242:1-6*.
42 Costanza MR, et. al. Value Health. 2018; 21 (Suppl 1):S167.
43 Boga M, et al. *Perf*. 2000; 15:143-150.
44 Kiziltepe U, et al. *Ann Thorac Surg* 2001;71:684–93.
45 Kazory A, et al. *Cardiorenal Med*. 2023;13(1)1-8.
46 Agostoni PG et al. *J Am Coll Cardiol*. 1993;21(2):424-31.

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

Components of the Aquadex System

The Aquadex System consists of:

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

Our Market Opportunity

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

Heart Failure

Heart disease is the leading cause of death in the United States and other developed countries. In fact, approximately 50% of patients who develop heart failure die within five years of diagnosis. The five-year mortality rate for heart failure, regardless of heart function, is approximately 75% across all phenotypes.[50] Approximately 6.7 million Americans over 20 years of age have heart failure, and the prevalence is expected to rise to 8.5 million Americans by 2030.[51] Based on the Atherosclerosis Risk in Communities Study from 2005 to 2013, conducted by the National Heart, Lung and Blood Institute, there are an estimated 960,000 new heart failure cases annually.[52] Annual hospitalizations for heart failure exceed one million in both the United States and Europe, and more than 90% are due to symptoms and signs of fluid overload.[53] In addition, approximately 68% of patients are discharged with sub-optimal results.[54] As such, there are over 600,000 heart failure patients in the United States who might benefit from new technologies to treat fluid overload.

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

47 Kazory A, et al. *Cardiorenal Med*. 2023;13(1)1-8.
48 Starr MC, et al. *Pediatric Nephrology*. 2024; 39(2):597-601.
49 Costanzo MR, et al. *J Am Coll Cardiol*. 2005; 46(11): 2047-51.
50 Shah, K, et al. *J Am Coll Cardiol*. 2017 Nov, 70 (20) 2476–2486.
51 Bozhurt B, et al. *J Card Fail*. *J Card Fail*. 2023; 29(10): 1412-42.
52 Benjamin EJ, et al. *Circ*. 2017;135:00-00. (e378).
53 Fonarow GC, et al. *Rev Cardiovasc Med*. 2003; 4: s21-30.
54 Testani JM, et al. *Circ Heart Fail*. 2016; 9(1): e002370.
55 Arrigo M et al. *Nat Rev Dis Primers*. 2020; 6(16):1-15.

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

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

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

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

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

The Company believes the total U.S. heart failure market is approximately $1 billion[62] and that roughly 30% of its revenue is derived from the treatment of heart failures patients.

Critical Care

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

The potential complications (e.g., renal failure, stroke, infection, arrhythmias, or prolonged intubation) are reported to be associated with high mortality, particularly when renal replacement therapy is required.[70] Major complications after cardiac operations are associated with an increased risk for operative death, longer hospital length of stay, and higher rates of discharge to a location other than home.[71]

56 Fonarow et al. *Rev Cardiovasc Med*. 2003;4: Suppl 7:S21-30.
57 Costanzo MR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445.
58 Sax D, et al. J Card Fail. 2022: 28(10): 1545-59.
59 Voigt J, et al. *Clin Cardiol*. 2014;37(5): 312–321.
60 Heidenreich PA, et al. *Circ Heart Fail*. 2013;6(3):606-619.
61 McIlvennan C et al. *Circ*. 2015; 131(20): 1796-1803.
62 See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.
63 https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/.
64 https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/.
65 Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.
66 Kruger A et al. *J Cardiovasc Dev Dis*. 2023;10(6);263-78.
67 Bowdish ME, et al. *Ann Thorac Surg*. 2021;111(6):1770-1780.
68 Xu J, et al. *Medicine*. 2015.94(33):e1360.
69 Xu J, et al. *Medicine*. 2015;94(33):e1360.
70 Granado RC et al. *BMC Nephro*. 2016;17:109-18.
71 Crawford TC, et al. *Ann Thorac Surg*. 2017;103:32-40.

Hospital readmissions are a common problem in cardiac surgery and remain high. Approximately 20% of patients who undergo cardiac operations require readmission, an outcome with significant health economic implications. Volume overload was among the top three most prevalent causes for first readmission within 30 days and beyond 30 days.[72] It is estimated that 13.5% of post cardiac surgery patients are readmitted due to fluid overload within 30 days of discharge, which equates to an estimated 70,000 fluid overload-related readmissions for CABG, valve, and VAD procedures per year in the United States.[73] Positive research has been recently published demonstrating the value of ultrafiltration in high-risk coronary artery bypass grafting surgery.[74] It is also encouraging to see ultrafiltration being recommended for cardiac surgery patients who are unresponsive to diuretics in a recently published turnkey order set proposed by the Enhanced Recovery After Surgery ("ERAS") Society consensus guidelines.[75]

The Company believes it can expand use cases for the Aquadex System, without any additional clinical trial or other labeling changes at the U.S. Food and Drug Administration ("FDA") to support its use in the applications identified immediately above.

The Company believes the total U.S. critical care failure market is approximately $900 million[76] and that approximately 40% of its revenue is derived from the treatment of critical care patients.

Pediatrics

Many of the conditions and procedures faced by adult patients also occur in pediatric patients, such as cardiac surgery, organ transplants, heart failure and ECMO therapy. Similar to adult patients, these conditions and procedures may lead to fluid overload. While incidence data is not readily available, it is estimated that there are approximately 10,000 to 14,000 pediatric patients with heart failure[77] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation.[78, 79, 80] Fluid overload drives pediatric morbidity and mortality risk in critically ill patients. In one pediatric study, a 3% increase in mortality was observed for every 1% increase in fluid overload, and children who are more than 20% fluid overloaded have an odds ratio for mortality of 8.5 compared to children who are less than 20% fluid overloaded.[81, 82]

The Company believes that the total U.S. pediatric market for fluid overload is approximately $130 million[83] and that roughly 30% of its revenue is derived from the treatment of pediatric patients.

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

72 Iribane A, et al. *Ann Thorac Surg*. 2014;98:1274-80.
73 Iribarne A, et al. *Ann Thorac Surg*. 2014 Oct; 98(4): 1274-80.
74 Beckles DL et al. *J Card Surg*.2022; 37: 2951-57.
75 Engelman D, et al. *Ann Thorac Surg*. 2023;115:11-5A
76 See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.
77 Jayaprasad, N. *Heart Views*. 2016; 17(3): 92–99.
78 https://www.cdc.gov/ncbddd/heartdefects/data.html.
79 Karamlou T, et al. *J Thorac Cardiovasc Surg*. 2013 Feb; 145(2):470-5.
80 https://www.organdonor.gov/about/donors/child-infant.html.
81 Sutherland SM, et al. *Am J Kidney Dis*. 2010; 55(2):315-25.
82 Gillespie RS, et al. Ped Nephro. 2004; 19(12):1394-99.
83 See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

It is because of this unmet medical need the Company has undertaken the development of a dedicated Continuous Renal Replacement Therapy ("CRRT") device intended for patients weighing between 2.5 and above kg. See – Product Development Activities below.

Growing Clinical Evidence

In December 2021, we launched the REVERSE-HF prospective, multicenter, randomized controlled trial (RCT) to evaluate ultrafiltration compared to IV diuretics in patients with heart failure. This RCT is currently being conducted at sixteen clinical sites nationwide, and patient enrollment began in June 2022. As of February 10, 2024, there are 91 patients enrolled in this RCT. The primary effectiveness endpoint is the time to first HF Event within 30 days, as a comparison between Aquadex therapy and IV Loop Diuretics. The Company intends to target a total of 20 sites and hopes to be fully enrolled by the middle of 2025 with a total of 372 patients enrolled. The protocol for REVERSE-HF permits an interim data analysis once enrollment reaches 80% of its targeted enrollment, and the Company hopes to complete analysis of the primary endpoint and to publish the results in the second half of 2025.

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

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

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

84 Watson R, et al. *Am Heart J Plus: Cardiol Res & Pract 24*. 2022; 1-6.
85 Watson R, et al. *Am Heart J Plus: Cardiol Res & Pract 24*. 2022; 1-6.
86 Kazory et al. *Cardiorenal Med*. 2023;13:1-8.
87 Kazory A, et al. *Cardio Renal Med*. 2023.12(1):1-8.
88 Costanzo MR, et al. *Val in Health.* 2018: 21(1): s167.

The AVOID-HF trial was initiated by Baxter International, Inc. (“Baxter”) in 2016. AVOID-HF was designed to prospectively address the question of patient outcomes when treated with ultrafiltration versus intravenous diuretics for acute decompensated heart failure. Trial design assumptions indicated that 810 patients would need to be randomized to achieve adequate statistical power. However, the study was terminated by Baxter at 224 patients, apparently for business reasons unrelated to patient outcomes or device safety. Despite being underpowered, the results of AVOID-HF indicated distinct trends toward reduced time to heart failure events within 90 days, favoring the ultrafiltration group over diuretics. In addition, pre-specified secondary endpoints demonstrated significant reductions in heart failure rehospitalizations and days in the hospital and cardiovascular events at 30 days. No significant differences were observed in creatinine level between the groups during treatment and up to 90 days following treatment. In totality, AVOID-HF provided evidence that had AVOID-HF been followed to completion, it is our belief that the trial would likely have met its primary endpoint of improved outcome in acute decompensated heart failure patients.[89]

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

Product Development Activities

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

Corporate Development Activities

SeaStar License and Distribution Agreement

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

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

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

Recent Developments

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

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

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

89 Costanzo MR, et al. *JACC: Heart Failure*. 2016;4(2):95-105.
90 Menon S, et al. *Clin J Am Soc Nephrol*. 2019;14(10):1432-1440.
91 Menon S, et al. *Clin J Am Soc Nephrol*. 2019;14(10):1432-1440.

The Company intends to continue actively monitoring the closing bid price for the Company's common stock between now and June 4, 2024, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

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 9 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 "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 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,[92] ECMO therapy[93], solid organ transplantation,[94] and kidney replacement therapy for neonatal patients. In February 2020, the Company received FDA 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 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.

92 Elliott MJ. *Ann Thorac Surg*. 1993;56:1518-22. fluid overload
93 Selewski DT, et al. *Crit Care Med*. 2012; 40(9): 2694-2699.
94 Riley AA. *BMC Nephrology*. 2018; 19:268-80.

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 granted a new and dedicated Category III Current Procedural Terminology (CPT) code, 0692T, for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver ultrafiltration to adult and pediatric patients weighing more than 20kg. In addition, the new CPT code provides additional reimbursement for therapeutic ultrafiltration administered in the outpatient setting and will facilitate the migration of the therapy to this setting for a subset of the patient population due to hospital economic and patient quality of life benefits. Continued focus on driving positive coverage policies for various targeted payers will be an ongoing strategy for the Company.

Outside the United States, the Aquadex System is sold by independent specialty distributors who in turn sell to hospitals and clinics in their geographic regions. We currently have distribution relationships in Austria, Belarus, Brazil, Colombia, Czech Republic, Germany, Greece, Hong Kong, India, Indonesia, 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 (as defined below) 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 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.[95]

Sales and Marketing

As of December 31, 2023, we had 24 full-time employees in sales and marketing. We have 9 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 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 FDA 510(k) clearance of the Aquadex SmartFlow® system for patients weighing over 20kg, we are also targeting pediatric hospitals. Our largest customer represented 13.9% of our 2023 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.

95 https://www.ncbi.nlm.nih.gov/pubmed/23833312

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.[96] 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.[97] 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.[98] The data suggests that the benefits of decongestion may outweigh modest or transient increases in serum creatinine during ultrafiltration. Thus, a change in creatinine should not dissuade the use of ultrafiltration.

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

In November 2020, we launched the ULTRA-PEDs pediatrics registry, a multi-center, single-arm study conducted at seven clinical sites, and closed in October 2023 with 97 patients enrolled and the data is currently being analyzed.

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,"*[99] 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, RCT to evaluate ultrafiltration compared to IV diuretics in patients with heart failure. This RCT is currently being conducted at nine clinical sites nationwide, and patient enrollment began in June 2022.

In February 2022, a third party retrospectively reviewed and concluded, *"The Use of Ultrafiltration as a fluid management strategy for High-Risk Coronary Artery Bypass Grafting,"*[100] 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.

96 Urban S, et al. *Adv Clin Exp Med*. 2021;30(7):737-746.
97 Grodin JL, et al. *Eur J of Heart Fail*. 2018;20(7):1148-1156.
98 Rao VS, et al. *Circ Heart Fail*. 2019;12 (6):e005552.
99 Urban S, et al. *Adv Clin Exp Med*. 2021;30(7):737-746.
100 Beckles D. et al. *J of Card Surg. Fail*. 2022; 37(10): 2951-2957.

A reanalysis of the AVOID-HF data was presented at the Annual Scientific Session of the Heart Failure Society of America in September 2022*, "Revisiting The Aquapheresis Versus Intravenous Diuretics And Hospitalizations For Heart Failure (AVOID-HF) Trial: Further Evidence Supporting Aquapheresis To Reduce Heart Failure Events,"*[101] using the novel Finkelstein-Schoenfeld method of hierarchical win ratio (WR) to explore cardiovascular mortality and heart failure 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.

In December 2022, a third-party, single center, real-world retrospective study of 335 patients treated with the Aquadex FlexFlow® System, *"Ten Year Real World Experience with Ultrafiltration for the Management of Acute Decompensated Heart Failure,"*[102] compared previous randomized controlled clinical trials with ultrafiltration and demonstrated that ultrafiltration compares favorably in reducing heart failure rehospitalizations (2.14 hospitalizations per year before Aquadex versus 0.4 hospitalizations per year one year after Aquadex), renal function response, and weight/volume loss. The study found ultrafiltration to be safe with regard to renal function (unchanged) despite the cohort in this study being sicker than those studied in other clinical trials, and that UF can be a safe and effective strategy for decongestion in clinical practice wherein the benefits outweigh the potential risks of kidney dysfunction requiring hemodialysis and major bleeding events.

In January 2023, we began designing an IDE clinical study for the Company's dedicated pediatric device currently under development. The design was reviewed with FDA in May 2023 and the study is anticipated to begin enrollment in 2024.

In September, 2023, a third-party, single center case study review of pediatric patients showed the Aquadex System successfully treated small patients without hemodynamic instability or other complications, demonstrating that therapy is an effective treatment option for fluid overload. Patient treatment was guided with the continuous hematocrit monitoring function built within the Aquadex System, supporting safe and effective fluid removal in critically ill pediatric patients.[103]

In November 2023, a retrospective cease series and literature review conducted by The Mount Sinai Hospital, "*Utilization of aquapheresis among hospitalized patients with end-stage liver disease: A case series and literature review,"* [104] utilization of ultrafiltration from January 2020 through July 2023 in patients with decompensated cirrhosis in the intensive care unit (ICU) found that the introduction of ultrafiltration earlier in a patient's hospital course may reduce the risk of kidney injury and diuretic-induced electrolyte derangement and reduce the risk of development of sequential organ failures in patients with decompensated cirrhosis.

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 2021 we 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 preliminary engineering testing 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.

101 Pinney S, et al. Poster from Heart Failure Society of America Meeting; October 2022; Washington, DC.
102 Hass DC, et al. *Amer Heart J Plus.; Cardio Res & Pract* 2022; 24:1-6 (100230)
103 Starr MC, et al. Pediatric Nephrology, September 2023
104 Crismale, J. et al. *Clinical Transplantation*, 2024; 38:e15221.

Manufacturers and Suppliers

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

Intellectual Property

We have submitted patent applications to establish an intellectual property portfolio through which we seek to protect our system and technology. In connection with our acquisition of the Aquadex Business, we entered into a patent license agreement with Baxter pursuant to which we obtained, for no additional consideration, a worldwide license to 49 exclusively licensed and 9 non-exclusively licensed patents used in connection with the Aquadex System to make, have made, use, sell, offer for sale and import the Aquadex System in the "field of use."

Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven "required maintenance patents," and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. We estimate that the patents licensed from Baxter will expire by mid-2026.

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

We have filed 10 patent applications related to our dedicated pediatric device in development. These resulted in 2 issued patents, 1 abandoned application, and 7 pending patent applications. The first issued patent involves a mechanical design for the therapy bags to allow easy load/unload by the user. The second issued patent involves transport mode operation on battery power, enabling patient mobility. Other 7 pending patent applications involve an extracorporeal blood filtration machine that includes flexible source line connection, open vs. closed loop fluid collection controls, a self-emptying bag, improved density measurement techniques, algorithm to ensure reliable auto clamp safety engagement, a blood leak detector that can detect hemolyzed blood, and mechanical cartridge design to ease manufacturing assembly and user setup.

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

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

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

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

Competition

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

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

Third-Party Reimbursement

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

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

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

Government Regulations

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

United States

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

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

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

The Aquadex FlexFlow system was granted FDA 510(k) clearance for commercial use on June 3, 2002. On February 4, 2020, we received 510(k) clearance of the Aquadex SmartFlow® system for use in adult and pediatric patients weighing 20 kg 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. Premarket clinical trials generally require submission of an application for an 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, but is not limited to, 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 studies or order it to establish and maintain a system for tracking its products through the chain of distribution to the patient level.

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

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

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

European Union

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

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

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

Employees

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

Legal Proceedings

We are not currently subject to any legal proceedings.

Company History

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

Corporate Information

Nuwellis, Inc. was incorporated in Delaware on August 22, 2002. We began operating our business in November 1999 through Sunshine Heart Company Pty Limited, which dissolved as a wholly owned Australian subsidiary of Nuwellis, Inc. in 2020. Our common stock began trading on 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 $20.2 million as of December 31, 2023. As of December 31, 2023, our accumulated deficit was $287.6 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 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 have sufficient capital to fund our operations through May 31, 2024. We will need to raise additional capital to fund our operations through the end of fiscal year 2024. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, the risk that we may not be able to continue as a going concern may make it more difficult to obtain necessary additional funding on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, require us to use our cash to make payments under such indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions. If we are unable to secure additional funding, our development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations.

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

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

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

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

We have identified a material weakness in connection with our internal control over financial reporting which, if not remediated, could adversely affect our business, reputation and stock price.

We review and update our internal controls, disclosure controls and procedures, and corporate governance policies as our Company continues to evolve. In addition, we are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("SOX") and management is required to report annually on our internal control over financial reporting. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of SOX until the date we are no longer a "smaller reporting company" as defined by applicable SEC rules.

Our management's evaluation of the effectiveness of our internal controls over financial reporting as of December 31, 2023, concluded that our controls were not effective, due to material weaknesses resulting from insufficient headcount to fully ensure adequate segregation of duties relating to the accounting and financial reporting function and the information technology function. Additionally, the company did not prepare and retain contemporaneous documentation to evidence the implementation and operation of controls, including controls related to the review of balance sheet reconciliations, the preparation and recording of journal entries, the review of period end financial reporting checklists and controls over user access. A material weakness is a deficiency or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's interim or annual condensed consolidated financial statements will not be prevented or detected on a timely basis.

Subject to limitations on liquidity that may prevent or delay additional hirings, the Company is planning to take steps to remediate these material weaknesses as soon as possible. We can give no assurance that these measures will remediate the material weakness in internal control, or that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that may lead to restatements of our financial statements or cause us to fail to meet our reporting obligations. Any such failure could also lead to reputational damage and a decrease in the market price of our stock.

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 50.4% of our revenues in the twelve months ended December 31, 2023, and 2022, respectively, with our largest customer representing 13.9% and 12.5%, respectively, of our revenues during such periods. Customer ordering patterns may vary significantly from quarter.

Customer ordering patterns may vary significantly from quarter to quarter, or customers may discontinue providing therapies using our products. If one of our largest customers reduced its purchases in a fiscal period, our revenues for that period may be materially adversely affected. Further, if one of our largest customers discontinued the use of our products, our revenues may be materially adversely affected.

We have limited commercial manufacturing experience and could experience difficulty in producing commercial volumes of the Aquadex System and related components or may need to depend on third parties for manufacturing.

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

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

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

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

Several hospitals in the U.S. included the Aquadex System in their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff are limited. However, we also experienced changes to our sales practices due to restrictions on hospital access and believe that such restrictions negatively affected revenue in other areas. In addition, the disruption created by COVID-19 created significant uncertainty about our ability to access the capital markets in future periods. The ongoing impact of the COVID-19 outbreak on our operational and financial performance has diminished, but we may still experience downstream effects that will depend on certain future developments, including the ongoing impact on our customers, hospital capital budget constraints, nursing staff shortages, hospital access restrictions imposed on our field employees, and effects on our vendors, all of which remain uncertain and cannot be predicted. 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.

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

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

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

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

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 Union 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 Notified Body. 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 Union Community and the United States.

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

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

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

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

We cannot assure you that our products will be safe or that there will not be serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products.

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

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

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

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

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

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

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

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

We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

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

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. The physician self-referral laws, commonly referred to as the Stark law, is a strict liability statute that generally prohibits physicians from making referrals for the furnishing of any "designated health services," for which payment may be made under the Medicare or Medicaid programs, to any entity with which the physician (or an immediate family member) has an ownership interest or compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self-referrals, regardless of the source of the payment for the patient's care. If it is determined that any of the relationships we may have with physicians violate the Stark law or similar statutes, we could become subject to civil and criminal penalties. The imposition of any such penalties could harm our business.

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

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

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

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

If we acquire other businesses, products or technologies, we could incur additional impairment charges and will be subject to risks that could hurt our business.

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

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

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

Risks Related to Our Intellectual Property

We may not be able to protect our intellectual property rights effectively, which could have an adverse effect on our business, financial condition or results of operations.

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

We have twenty 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.

We have filed 10 patent applications related to our dedicated pediatric device in development. These resulted in 2 issued patents, 1 abandoned application, and 7 pending patent applications. The first issued patent involves a mechanical design for the therapy bags to allow easy load/unload by the user. The second issued patent involves transport mode operation on battery power, enabling patient mobility. Other 7 pending patent applications involve an extracorporeal blood filtration machine that includes flexible source line connection, open vs. closed loop fluid collection controls, a self-emptying bag, improved density measurement techniques, algorithm to ensure reliable auto clamp safety engagement, a blood leak detector that can detect hemolyzed blood, and mechanical cartridge design to ease manufacturing assembly and user setup.

In addition, as of January 30, 2024, we owned 16 issued patents and 14 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 and the Health Information Technology for Clinical and Economic Health Act 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

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

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

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

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

The Company intends to continue actively monitoring the closing bid price for the Company's common stock between now and June 4, 2024, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

If our common stock is delisted from Nasdaq, our ability to raise capital through public offerings of our securities and to finance our operations could be adversely affected. We also believe that delisting would likely result in decreased liquidity and/or increased volatility in our common stock and could harm our business and future prospects. In addition, we believe that, if our common stock is delisted, our stockholders would likely find it more difficult to obtain accurate quotations as to the price of the common stock and it may be more difficult for stockholders to buy or sell our common stock at competitive market prices, or at all.

If our common stock is delisted, our common stock would likely then trade only in the over-the-counter market. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage for our Company; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the "penny stock" rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. If our common stock is delisted from Nasdaq and it trades on the over-the-counter market at a price of less than $5.00 per share, our common stock would be considered a penny stock. The SEC's penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock.

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

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

As of December 31, 2023, there were 127 shares of Series F Convertible Redeemable Preferred Stock, par value $0.0001 per share (the "Series F Convertible Preferred Stock") outstanding, convertible into 125,857 shares of common stock. The certificate of designation for our Series F Convertible Preferred Stock contains an anti-dilution provision, which provision requires the lowering of the applicable conversion price, as then in effect, to the purchase price per share of common stock or common stock equivalents issued in the future. If the effective price per share on a common-stock equivalent basis in a future equity offering is lower than the then-current conversion price of the Series F Convertible Preferred Stock, then such conversion price shall be reduced to such lower price and additional shares of common stock will be issuable upon the conversion of the of the Series F Convertible Preferred Stock. To the extent the outstanding shares of Series F Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will experience further dilution.

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

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

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

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

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

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

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

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

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

On December 9, 2022, we effected a 1-for-100 reverse split of our outstanding common stock. This reverse stock split did not change the par value of our common stock or the number of common or preferred shares authorized by our Fourth Amended and Restated Certificate of Incorporation, as amended (our "Certificate of Incorporation"). Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of December 31, 2023 our Certificate of Incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F Convertible Preferred Stock, 600,000 of which are designated Series J Convertible Redeemable Preferred Stock and we have 5,682,461 shares of common stock outstanding, 3,495,757 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, 66,917 Series J Convertible Preferred Stock issuable upon the exercise of 133,834 warrants issued in the October 2023 Offering, and 41,871 shares of common stock reserved for future grant under the Company's equity incentive plans.

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

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

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

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

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

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

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

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

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

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

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

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

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

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 1C. Cybersecurity.

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. We value the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things: operational risks, intellectual property theft, fraud, extortion, harm to employees or customers and violation of data privacy or security laws.

We have a cross-departmental approach to addressing cybersecurity risk, including input from employees [from our information technology department], our senior vice president of operations and engineering, and our board of directors. The board of directors, Audit Committee, and senior and management devote significant resources to cybersecurity and risk management processes to adapt to the changing cybersecurity landscape and respond to emerging threats in a timely and effective manner. Our cybersecurity risk management protocols are comprised of software programs including antivirus protection, end-point threat detection, remote access, multifactor authentication. In addition, we have a set of Company-wide policies and procedures concerning cybersecurity matters, which include an employee handbook as well as other policies that directly or indirectly relate to cybersecurity, such as policies related to incident response, confidential information and the use of internet, social media, email and wireless. These policies go through an internal review process and are approved by our senior vice president of operations and engineering.

Our Senior Vice President of Operations and Engineering is responsible for developing and implementing our information security program and reporting on cybersecurity matters to the board of directors. Nuwellis leverages 3rd party IT service provider and specifically their cybersecurity team's expertise.

All employees are required to complete cybersecurity training as part of on-boarding process and on-going training both online and in-person. IT department assigns position specific security level encryption to manage information security

We have continued to expand investments in IT security, including software programs and policies mentioned above. We regularly test defenses by performing simulations and drills at both a technical level (including through penetration tests) and by reviewing our operational policies and procedures with third-party experts. At the management level, our IT security team regularly monitors alerts and meets to discuss threat levels, trends and remediation.] In addition to assessing our own cybersecurity preparedness, we also consider and evaluate cybersecurity risks associated with use of third-party service providers.

The Audit Committee and the full board of directors periodically participate in discussions with management and amongst themselves regarding cybersecurity risks. As of 2023 the Audit Committee performs an annual review of the Company's cybersecurity program, which includes discussion of management's actions to identify and detect threats, as well as planned actions in the event of a response or recovery situation. The Audit Committee's annual review also includes review of recent enhancements to the Company's defenses and management's progress on its cybersecurity strategic roadmap.

Our board of directors has ultimate oversight of cybersecurity risk, which it manages as part of our risk management processes. That program is utilized in making decisions with respect to company priorities, resource allocations, and oversight structures. Although the board members are former executives of publicly traded companies, none of them have specific cybersecurity experience.

We face a number of cybersecurity risks in connection with our business. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we have, from time to time, experienced threats to and breaches of our data and systems, including malware and computer virus attacks. Such occurrences could negatively impact our business strategy, reputation and results of operation. For more information about the cybersecurity risks we face, see our risk factors in Item 1A- Risk Factors in this Annual Report on Form 10-K.

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 $34,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease.

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

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 the Nasdaq Capital Market, 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 March 1, 2024, we had 6,801,443 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.

Recent Sales of Unregistered Securities. Except as previously disclosed on our Current Report on Form 8-K dated June 19, 2023, respecting the issuance of a warrant to Davita Inc. to purchase up to an aggregate of 1,289,081 shares of common stock of the Company at an exercise price of $3.2996 per share, there have been no sales of unregistered securities during the year ended December 31, 2023.

ITEM 6. [Reserved].

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 device 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 has diminished, but we may still experience downstream effects that will depend on certain future developments, including the ongoing impact on our customers, hospital capital budget constraints, nursing staff shortages, hospital access restrictions imposed on our field employees, and effects on our vendors, all of which remain uncertain and cannot be predicted.

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 1A "Risk Factors" in this Annual Report on Form 10-K.

Recent Developments

Public Offerings

On October 12, 2023, the Company entered into a Placement Agency Agreement (the "Placement Agency Agreement") with Lake Street Capital Markets, LLC and Maxim Group LLC, pursuant to which the Company issued and sold, in a best efforts registered public offering by the Company (the "October 2023 Offering"), 150,000 units, with each Unit consisting of (A) one share of the Company's Series J Convertible Redeemable Preferred Stock, par value $0.0001 per share, and (B) one warrant to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock, at a price to the public of $15.00 per Unit, less placement agent fees and commissions. The public offering price of $15.00 per Unit reflects the issuance of the Series J Convertible Preferred Stock with an original issue discount of 40%. The Company also registered under the Registration Statement (as defined below) an additional 362,933 shares of Series J Convertible Preferred Stock that will be issued, if and when the Company's board of directors declares such dividends, as paid in-kind dividends and the shares of the Company's common stock issuable upon conversion of the Series J Convertible Preferred Stock issued as PIK dividends.

The Units, the shares of Series J Convertible Preferred Stock, the Warrants, the PIK Dividend Shares, the PIK Conversion Shares as well as the shares of Series J Convertible Preferred Stock issuable upon exercise of the Warrants and the shares of the Company's common stock, par value $0.0001 per share, issuable upon conversion of the Series J Convertible Preferred Stock, were offered and sold by the Company pursuant to an effective registration statement on Form S-1, as amended (File No. 333-274610), which was initially filed with the SEC on September 21, 2023, as amended on September 29, 2023, and declared effective by the SEC on September 29, 2023 with an additional registration statement on Form S-1 filed on October 6, 2023 pursuant to Rule 462(c). A final prospectus relating to the Offering was filed with the SEC on October 13, 2023. The closing of the October 2023 Offering contemplated by the Placement Agency Agreement occurred on October 17, 2023.

On October 17, 2023, the Company also entered into a warrant agency agreement with the Company's transfer agent, Equiniti Trust Company, LLC, who will act as warrant agent for the Company, setting forth the terms and conditions of the Warrants sold in the October 2023 Offering.

Each Warrant has an exercise price of $7.50 per one-half of one (0.5) share of Series J Convertible Preferred Stock, is immediately exercisable and will expire three (3) years from the date of issuance.

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

The gross proceeds to the Company from the October 2023 Offering were $2.25 million. Net proceeds were approximately $1.5 million after deducting placement agent fees and commissions and offering expenses payable by the Company. The Company used the net proceeds from the October 2023 Offering for working capital and for general corporate purposes.

The Series J Convertible Preferred Stock will be reflected as mezzanine equity and accreted to reflect its redemption value as of each reporting date. The accretion will be reflected as a deemed dividend adjustment to arrive at net loss attributed to common stockholders for earnings per share calculations.

The warrants will be reflected as a liability and re-measured at fair value as of each reporting date with fair value changes being recorded as non-operating income or expense. The warrants were valued on day 1 and exceeded the gross proceeds of the offering. This resulted in a day 1 financing expense of $2.7 million.

Nasdaq Notice

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

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

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

The Company intends to continue actively monitoring the closing bid price for the Company's common stock between now and June 4, 2024, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that the Company will regain compliance with the Minimum Bid Price Requirement during the 180-day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

Expense Reduction Initiatives

Understanding the near-term need to raise capital, the Company has recently undertaken steps to reduce our monthly cash burn rate by approximately 40%, balanced against our strategic growth initiatives, which will provide more flexibility in anticipation of tougher capital market conditions for microcap companies like Nuwellis. These reductions include, but are not limited to the following: selected job eliminations, a reduction of the salaries for members of senior management, no merit increases to the base salaries of any named executive officer or employee in 2024 for performance provided during the fiscal year ended December 31, 2023, no cash bonuses to any named executive officer or employee in 2024 for performance provided during the fiscal year ended December 31, 2023, a reduction in Board of Director and committee fees, temporary suspension of company 401k match, travel reductions, and reductions to select professional services.

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, 2023, 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 and convertible preferred 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 initially measure the fair value of the warrants upon issuance and subsequently 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 grant date 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, 2023, includes a deemed dividend from the Series J Convertible Preferred Stock of $2.3 million and a payment in kind dividend from the Series J Convertible Preferred Stock of $0.1 million. (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 its market capitalization determined with level 1 fair value inputs. There have been no impairment losses recognized for the years ended December 31, 2023, or December 31, 2022.

Going Concern

Our Consolidated financial statements have been prepared and presented on a basis assuming we continue as a going concern. During the years ended December 31, 2023, and 2022, 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, 2023, we had an accumulated deficit of $287.6 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, investing in new product development, 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, 2023, we closed on underwritten public and other equity offerings for aggregate net proceeds of approximately $40.9 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 May 31, 2024; however, there can be no assurance of this. We intend to 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. The Company has adopted the new standard effective January 1, 2023, which didn't have a material impact on the 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, 2023, we had an accumulated deficit of $287.6 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
(in thousands)

Year Ended December 31, 2023	Year Ended December 31, 2022	Increase (Decrease)	% Change
$ 8,864	$ 8,543	$ 321	3.8%

Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with the Aquadex System consoles. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We sell outside 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, 2023, increased over the prior year due to higher circuit sales, service-related revenue, and International sales partially offset by a decrease in console sales.

Costs and Expenses
Our costs and expenses were as follows:

(in thousands)	Year Ended December 31, 2023	Year Ended December 31, 2022	Increase (Decrease)	% Change
Cost of goods sold	$ 3,881	$ 3,788	$ 93	2.5%
Selling, general and administrative	$ 17,191	$ 17,584	$ (393)	(2.2 %)
Research and development	$ 5,422	$ 4,342	$ 1,080	24.9%

Cost of Goods Sold
The increase in costs of goods sold for the year ended December 31, 2023, compared to the year ended December 31, 2022, was primarily due to lower fixed overhead absorption because of lower manufacturing volumes.

Selling, General and Administrative
The decrease in selling, general and administrative expense primarily reflects decreased headcount and compensation related expenses during the year.

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

In the current year period, the company recorded a non-recurring expense reduction of approximately $800 thousand, reducing incentive compensation, impacting both SG&A and R&D. Additionally, the company recorded a $550 thousand SG&A expense, in the current year period, for contractual spend related to the SeaStar license and distribution agreement.

Income Tax Expense

(in thousands)	Year Ended December 31, 2023	Year Ended December 31, 2022	Increase (Decrease)	% Change
Income tax expense	$ 8	$ 9	$ (1)	(11.1%)

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 March 1, 2024 our Certification of Incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F Convertible Preferred Stock, and 600,000 of which are designated Series J Convertible Preferred Stock, and we have 6,801,443 shares of common stock outstanding, 2,376,920 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, and 1,459,336 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 Convertible 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.

The warrants were reflected as a liability and were valued on day 1. The valuation exceeded the gross proceeds of the offering, which resulted in a day 1 financing expense of $7.7 million. The warrants were re-measured at fair value as of December 31, 2022, with the fair value change being recorded as non-operating income.

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. In connection with the October 2023 offering, the conversion price of the Series F convertible preferred stock was reduced from $25 to $1.01, the per share price to the public in the October 2023 offering, described below.

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 March 2023, the Company filed a Prospectus Supplement to its Registration Statement on Form S-3 with the SEC in connection with a proposed At-the-Market Securities offering (the “At-the-Market Program”). During 2023, the Company issued 657,333 shares of common stock under the At-the-Market Program for gross proceeds of approximately $2.3 million. Net proceeds totaled approximately $2.1 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

On October 12, 2023, the Company entered into the Placement Agency Agreement with the Placement Agents, pursuant to which the Company issued and sold, in a best efforts registered public offering, 150,000 Units, with each Unit consisting of (A) one share of Series J Convertible Preferred Stock, and (B) one warrant to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock, at a price to the public of $15.00 per Unit, less placement agent fees and commissions. The public offering price of $15.00 per Unit reflects the issuance of the Series J Convertible Preferred Stock with an OID of 40%. The Company also registered under the Registration Statement the PIK Dividends Shares that will be issued, if and when the Company’s Board of Directors declares such PIK dividends and the PIK Conversion Shares.

The Units, the shares of Series J Convertible Preferred Stock, the Warrants, the PIK Dividend Shares, the PIK Conversion Shares as well as the shares of Series J Convertible Preferred Stock issuable upon exercise of the Warrants and the shares of the Company’s common stock, issuable upon conversion of the Series J Convertible Preferred Stock, were offered and sold by the Company pursuant to the Registration Statement, which was initially filed with the SEC on September 21, 2023, as amended on September 29, 2023, and declared effective by the SEC on September 29, 2023 with an additional registration statement on Form S-1 filed on October 6, 2023 pursuant to Rule 462(c). A final prospectus relating to the October 2023 Offering was filed with the SEC on October 13, 2023. The closing of the October 2023 Offering contemplated by the Placement Agency Agreement occurred on October 17, 2023.

On October 17, 2023, the Company also entered into the Warrant Agency Agreement with the Company’s transfer agent, Equiniti Trust Company, LLC, who will act as warrant agent for the Company, setting forth the terms and conditions of the Warrants sold in the October 2023.

Each Warrant has an exercise price of $7.50 per one-half of one (0.5) share of Series J Convertible Preferred Stock, is immediately exercisable and will expire three (3) years from the date of issuance.

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

The gross proceeds to the Company from the October 17, 2023, Offering were $2.25 million. Net proceeds were approximately $1.5 million after deducting placement agent fees and commissions and Offering expenses payable by the Company. The Company used the net proceeds from the Offering for working capital and for general corporate purposes.

The Series J Convertible Preferred Stock will be reflected as mezzanine equity and accreted to reflect its redemption value as of each reporting date. The accretion will be reflected as a deemed dividend adjustment to arrive at net loss attributed to common stockholders for earnings per share calculations.

The warrants will be reflected as a liability and re-measured at fair value as of each reporting date with fair value changes being recorded as non-operating income or expense. The warrants were valued on day 1 and exceeded the gross proceeds of the offering. This resulted in a day 1 financing expense of $2.7 million.

As of December 31, 2023, and 2022, cash, cash equivalents, and marketable securities were $3.8 million and $18.3 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 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 $17.9 million and $15.1 million in 2023 and 2022, 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 and warrant financing expense for the current year period.

Cash Flows from Investing Activities

Net cash provided by investing activities was $0.3 million and $14.7 million in 2023 and 2022, 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 $3.7 million and $9.4 million in 2023 and 2022, 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. In 2023, the Company also participated in an "At-the-Market Program" resulting in additional proceeds.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2023, which represent material expected or contractually committed future obligations:

(in thousands)	Payments Due by Period				
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Operating Lease	$ 257	$ 536	$ 69	$ -	$ 862
Financing Leases	-	-	-	-	-
Total	$ 257	$ 536	$ 69	$ -	$ 862

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 $34,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease. 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, 2023, 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, 2023 and 2022, 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, 2023 and 2022, and the results of its operations and 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 its 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 matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was 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 a critical audit matter 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 matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

EVALUATION OF WARRANT LIABILITY

Critical Audit Matter Description

As described in Notes 4 and 6 to the consolidated financial statements, the Company has certain common stock and convertible preferred stock warrants which are 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 convertible preferred stock warrants on the date of issuance and as of December 31, 2023, using a Monte Carlo simulation model. The Company determined the fair value of the common stock warrants prior to conversion to common stock using a Monte Carlo simulation model.

We identified the assessment of the measurements of fair value of the 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:

- With the assistance of firm personnel having specialized skills and knowledge, we tested the models and methodologies used to calculate the fair value of the warrants at each measurement date 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 11, 2024

NUWELLIS, INC. AND SUBSIDIARY
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,800	$ 17,737
Marketable securities	—	569
Accounts receivable	1,951	1,406
Inventories, net	1,997	2,661
Other current assets	461	396
Total current assets	8,209	22,769
Property, plant and equipment, net	728	980
Operating lease right-of-use asset	713	903
Other assets	120	21
TOTAL ASSETS	$ 9,770	$ 24,673
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 2,380	$ 2,245
Accrued compensation	525	2,161
Current portion of operating lease liability	216	196
Current portion of finance lease liability	—	28
Other current liabilities	51	58
Total current liabilities	3,172	4,688
Common stock warrant liability	2,843	6,868
Operating lease liability	544	760
Total liabilities	6,559	12,316
Commitments and contingencies		
Mezzanine Equity		
Series J Convertible Preferred Stock as of December 31, 2023 and December 31, 2022, par value $0.0001 per share; authorized 600,000 and none, issued and outstanding 11,950 and none, respectively	221	—
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2023 and December 31, 2022, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of December 31, 2023 and December 31, 2022, par value $0.0001 per share; authorized 18,000 shares, issued and outstanding 127 shares	—	—
Series I convertible preferred stock as of December 31, 2023 and December 31, 2022, par value $0.0001 per share; authorized 1,049,280 shares, issued and outstanding none and 1,049,280, respectively	—	—
Preferred stock as of December 31, 2023 and December 31, 2022, par value $0.0001 per share; authorized 39,802,000 shares, none outstanding	—	—
Common stock as of December 31, 2023 and December 31, 2022, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 5,682,461 and 536,394, respectively	1	—
Additional paid-in capital	290,646	279,736
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(31)	(18)
Unrealized gain (loss) on marketable securities	—	56
Accumulated deficit	(287,626)	(267,417)
Total stockholders' equity	2,990	12,357
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 9,770	$ 24,673

See notes to the consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARY

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	**2022**
Net sales	$ 8,864	$ 8,543
Cost of goods sold	3,881	3,788
Gross profit	4,983	4,755
Operating expenses:		
Selling, general and administrative	17,191	17,584
Research and development	5,422	4,342
Total operating expenses	22,613	21,926
Loss from operations	(17,630)	(17,171)
Other income (expense), net		
Other income	154	75
Financing expense	(3,483)	(9,247)
Change in fair value of warrant liability	758	11,827
Loss before income taxes	(20,201)	(14,516)
Income tax expense	(8)	(9)
Net loss	(20,209)	(14,525)
Deemed dividend attributable to Series J Convertible Preferred Stock	(2,297)	—
Dividend on Series J Convertible Preferred Stock	(121)	—
Net loss attributable to common stockholders	$ (22,627)	$ (14,525)
Basic and diluted loss per share	$ (11.52)	$ (83.55)
Weighted average shares outstanding – basic and diluted	1,964,406	173,846
Other comprehensive loss:		
Net loss	$ (20,209)	$ (14,525)
Unrealized (loss) gain on marketable securities	(56)	80
Unrealized foreign currency translation adjustment	(13)	(7)
Total comprehensive loss	$ (20,278)	$ (14,452)

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, 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	—	—	862	—	—	862
Issuance of common stock, net	209,940	—	—	—	—	—
Issuance of common stock from preferred series I stock conversions	221,078	—	—	—	—	—
Balance December 31, 2022	536,394	—	279,736	38	(267,417)	12,357
Net loss	—	—	—	—	(20,209)	(20,209)
Unrealized foreign currency translation adjustment	—	—	—	(13)	—	(13)
Unrealized gain on marketable securities	—	—	—	(56)	—	(56)
Stock-based compensation	—	—	670	—	—	670
Issuance costs related to 2022 common stock offering	—	—	(11)	—	—	(11)
Issuance of common stock from preferred series I stock conversions	10,493	—	—	—	—	—
Issuance of common stock from exercise of warrants	1,061,162	—	307	—	—	307
Reclassification of warrants to equity	—	—	7,623	—	—	7,623
Issuance of common stock from ATM offering, net	657,333	—	2,119	—	—	2,119
Issuance of common stock from conversion of Series J Convertible Preferred Stock	3,417,079	1	2,620	—	—	2,621
Series J Convertible Preferred Stock deemed dividend	—	—	(2,297)	—	—	(2,297)
Series J Convertible Preferred Stock PIK dividend	—	—	(121)	—	—	(121)
Balance December 31, 2023	5,682,461	$ 1	$ 290,646	$ (31)	$ (287,626)	$ 2,990

See notes to the consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows
(in thousands)

	For the years ended December 31,	
	2023	**2022**
Operating Activities		
Net loss	$ (20,209)	$ (14,525)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	362	372
Stock-based compensation expense	670	862
Change in fair value of warrant liability	(758)	(11,827)
Financing expense	3,483	9,247
Net realized and unrealized gains on marketable securities	(65)	124
Changes in operating assets and liabilities:		
Accounts receivable	(545)	(656)
Inventory	697	140
Other current assets	(65)	(68)
Other assets and liabilities	(7)	(96)
Accounts payable and accrued expenses	(1,500)	1,278
Net cash used in operations	(17,937)	(15,149)
Investing activities:		
Additions to intangible assets	(99)	—
Proceeds from sales of marketable securities	578	14,850
Purchase of property and equipment	(149)	(122)
Net cash provided by investing activities	330	14,728
Financing activities:		
Proceeds from public stock offerings, net	2,109	9,449
Proceeds from Series J Preferred Stock and Warrants	1,482	—
Proceeds from the exercise of warrants	120	—
Payments on finance lease liability	(28)	(26)
Net cash provided by financing activities	3,683	9,423
Effect of exchange rate changes on cash	(13)	(7)
Net increase in cash and cash equivalents	(13,937)	8,995
Cash and cash equivalents—beginning of year	17,737	8,742
Cash and cash equivalents—end of year	$ 3,800	$ 17,737
Supplemental schedule of non-cash activities		
Inventory transferred to property, plant and equipment	$ 41	$ 42
Issuance of Common Stock for exercise of Series I Warrants	$ 7,623	$ —
Issuance of Series J Preferred Stock for exercise of Warrants	$ 2,927	$ —
Deemed dividend on Series J Preferred Stock	$ 2,297	$ —
Series J Preferred Stock issued for payment in kind dividend	$ 121	$ —
Supplemental cash flow information		
Cash paid for income taxes	$ 12	$ 9

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.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's chief executive officer, views the Company's operations and manages its business as a single operating segment. At December 31, 2023 and 2022, long-lived assets were located primarily in the United States.

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, 2023 and 2022, 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, 2023, the Company had an accumulated deficit of $287.6 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, 2023, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately $40.9 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 May 31, 2024. However, the Company will seek to raise additional capital to support its growth or other strategic initiatives through debt, equity, or a combination thereof. There can be no assurance we will be successful in raising additional capital.

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).

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, 2023, or December 31, 2022. As of December 31, 2023, two customers represented 14% and 15% of the total accounts receivable balance. As of December 31, 2022, two customers represented 15% and 10% 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:

(in thousands)	**2023**	**2022**
Finished Goods	$ 393	$ 993
Work in Process	207	204
Raw Materials	1,472	1,609
Inventory Reserve	(75)	(145)
Total	$ 1,997	$ 2,661

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 and amortization expense was $362,000 and $372,000 for the years ended December 31, 2023, and 2022, 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 its market capitalization determined with level 1 fair value inputs. For the operating lease right-of-use asset the Company believes that the remaining lease payments represent a fair value of the right of use asset.

There have been no impairment losses recognized for the years ended December 31, 2023, or 2022.

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, 2023, two customers represented 13.9% and 12.6% of net sales. For the year ended December 31, 2022, one customer represented 12.5% 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 recorded 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, 2023, includes a deemed dividend from the Series J Convertible Preferred Stock of $2.3 million and a payment in kind dividend from the Series J Convertible Preferred Stock of $0.1 million. (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,	
	2023	**2022**
Stock options	110,916	10,485
Warrants to purchase common stock	2,963,192	679,244
Series F convertible preferred stock	125,857	5,080
Series I convertible preferred stock	—	10,493
Series J convertible preferred stock	295,792	—
Total	3,495,757	705,302

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)	**2023**	**2022**
Net loss to common stockholders	$ (20,209)	$ (14,525)
Deemed dividend attributable to Series J Convertible Preferred Stock	(2,297)	—
Dividend on Series J Convertible Preferred Stock	(121)	—
Net loss after deemed dividend	(22,627)	(14,525)
Weighted average shares outstanding	1,964	174
Basic and diluted loss per share	$ (11.52)	$ (83.55)

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. The Company has adopted the new standard effective January 1, 2023, which didn't have a material impact on the 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, Belarus, Brazil, Colombia, Czech Republic, Germany, Greece, Hong Kong, India, Indonesia, Israel, Italy, Panama, Romania, Singapore, Slovak Republic, 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, 2023, and 2022. The unfulfilled performance obligations related to these extended service plans are included in deferred revenue, which is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

Sales taxes and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Revenue includes shipment and handling fees charged to customers. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

Product Returns: The Company offers customers a limited right of return for its 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 received minimal returns to date and believes that future returns of its products will continue to 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, 2023	December 31, 2022
Production Equipment	$ 1,360	$ 1,360
Loaners and Demo Equipment	1,534	1,444
Computer Software and Equipment	688	719
Office Furniture & Fixtures	375	375
Leasehold Improvements	253	253
Total	4,210	4,151
Accumulated Depreciation	(3,482)	(3,171)
	$ 728	$ 980

Depreciation and amortization expense was $362,000 and $372,000 for the years ended December 31, 2023, and 2022, respectively.

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. In connection with the October 2023 offering, the conversion price of the Series F convertible preferred stock was reduced from $25 to $1.01, the per share price to the public in the October 2023 offering, described below.

As of December 31, 2023 and December 31, 2022, 127 shares of the Series F convertible preferred stock remained outstanding.

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, 2023.

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.

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, 2023 and 2022, there were 6,532 warrants outstanding.

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 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.

The warrants were reflected as a liability and were valued on day 1. The valuation exceeded the gross proceeds of the offering, which resulted in a day 1 financing expense of $7.7 million. The warrants were re-measured at fair value as of December 31, 2022, with the fair value change being recorded as non-operating income.

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. On December 9, 2022, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on December 9, 2022, and the Company's common stock began trading on a split-adjusted basis when the market opened on December 12, 2022. The conversion price of the preferred stock issued in the 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. In connection with the October 2023 offering, the conversion price of the Series F convertible preferred stock was reduced from $25 to $1.01, the per share price to the public in the October 2023 offering, described below.

Reverse Stock Split: On December 5, 2022, the Company's stockholders approved 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.

2023 At-the-Market Program: In March 2023, the Company filed a Prospectus Supplement to its Registration Statement on Form S-3 with the SEC in connection with a proposed At-the-Market Securities offering (the "At-the-Market Program"). During 2023, the Company issued 657,333 shares of common stock under the At-the-Market Program for gross proceeds of approximately $2.3 million. Net proceeds totaled approximately $2.1 million after deducting the underwriting discounts and commissions and other costs associated with the offering.

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

October 2023 Offering: On October 12, 2023, Nuwellis, Inc. entered into a Placement Agency Agreement with Lake Street Capital Markets, LLC and Maxim Group LLC, pursuant to which the Company issued and sold, in a best efforts registered public offering by the Company, 150,000 units, with each Unit consisting of (A) one share of the Company's Series J Convertible Redeemable Preferred Stock, par value $0.0001 per share, and (B) one warrant to purchase one-half of one (0.50) share of Series J Convertible Preferred Stock, at a price to the public of $15.00 per Unit, less placement agent fees and commissions. The public offering price of $15.00 per Unit reflects the issuance of the Series J Convertible Preferred Stock with an original issue discount of 40%. The Company is also registering under the Registration Statement (as defined below) an additional 362,933 shares of Series J Convertible Preferred Stock that will be issued, if and when the Company's Board of Directors declares such dividends, as paid in-kind dividends and the shares of Common Stock issuable upon conversion of the Series J Convertible Preferred Stock issued as PIK dividends.

The Units, the shares of Series J Convertible Preferred Stock, the Warrants, the PIK Dividend Shares, the PIK Conversion Shares as well as the shares of Series J Convertible Preferred Stock issuable upon exercise of the Warrants and the shares of the Company's common stock, par value $0.0001 per share, issuable upon conversion of the Series J Convertible Preferred Stock, were offered and sold by the Company pursuant to an effective registration statement on Form S-1, as amended (File No. 333-274610), which was initially filed with the Securities Exchange Commission on September 21, 2023, as amended on September 29, 2023, and declared effective by the SEC on September 29, 2023 with an additional registration statement on Form S-1 filed on October 6, 2023 pursuant to Rule 462(c). A final prospectus relating to the Offering was filed with the SEC on October 13, 2023. The closing of the Offering contemplated by the Placement Agency Agreement occurred on October 17, 2023.

On October 17, 2023, the Company also entered into a warrant agency agreement with the Company's transfer agent, Equiniti Trust Company, LLC, who will act as warrant agent for the Company, setting forth the terms and conditions of the Warrants sold in this Offering.

Each Warrant has an exercise price of $7.50 per one-half of one (0.5) share of Series J Convertible Preferred Stock, is immediately exercisable and will expire three (3) years from the date of issuance.

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

The gross proceeds to the Company from the October 17, 2023, Offering were $2.25 million. Net proceeds were approximately $1.5 million after deducting placement agent fees and commissions and Offering expenses payable by the Company. The Company used the net proceeds from the Offering for working capital and for general corporate purposes.

The Series J Convertible Preferred Stock is classified as mezzanine equity and accreted to reflect its redemption value as of each reporting date. The accretion will be reflected as a deemed dividend adjustment to arrive at net loss attributed to common stockholders for earnings per share calculations.

The warrants are recorded as a liability and re-measured at fair value as of each reporting date with fair value changes being recorded as non-operating income or expense. The warrants were valued on day 1 and exceeded the gross proceeds of the offering. This resulted in a day 1 financing expense of $2.7 million.

Underwriter and Placement Agent Fees: In connection with the offerings described above, the Company paid the underwriter or placement agent, as applicable, an aggregate cash fee equal to 8% of the aggregate gross proceeds raised in each of the offerings, except with respect to the issuances made pursuant to the At-the-Market Program, for which the placement fee was equal to 3% of the aggregate gross proceeds.

In conjunction with the Supply Agreement, the Company issued DaVita a warrant to purchase up to an aggregate of 1,289,081 shares of common stock of the Company, par value $0.0001 per share, at an exercise price of $3.2996 per share, provided that at no time can the DaVita Warrant be exercised for an amount of shares that would represent greater than 19.9% ownership in the Company subject to certain vesting milestones. The DaVita Warrant is expected to vest in four tranches as follows: (i) 25% upon receipt of notice to extend the Supply Agreement past the initial pilot-term; (ii) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within twelve months of Ultrafiltration Services Approval; (iii) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within twenty-four months of Ultrafiltration Services Approval; and (iv) 25% upon the attainment by the Company of a net revenue achievement from DaVita's efforts pursuant to the Supply Agreement within thirty-six months of Ultrafiltration Services Approval. This warrant had not vested as of December 31, 2023.

The Company evaluated the accounting treatment for the DaVita Warrant pursuant to ASC 718, "Stock Compensation," and ASC 480, "Distinguishing Liabilities from Equity," and concluded that the DaVita Warrant should be classified as an equity instrument on the balance sheet as of December 31, 2023. In accordance with this treatment, the Company's management concluded none of the performance-based vesting conditions of the DaVita Warrant were probable of vesting as of December 31, 2023, and therefore, no expense associated with the DaVita Warrant was recognized in the Company's financial statements as of that date. The Company will continue to evaluate the probability of achieving the performance milestones associated with the DaVita Supply Agreement and will record the related equity-based expense in its financial statements based on the grant date fair value of the DaVita Warrant when management deems it is probable that the performance-based vesting conditions will be achieved.

Note 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 $670,000 and $862,000 during the years ended December 31, 2023 and 2022, 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,

(in thousands)	2023	2022
Selling, general and administrative	$ 630	$ 784
Research and development	40	78
Total	$ 670	$ 862

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:

	2023		2022	
	Options Outstanding	Weighted Average Exercise Price	Options Outstanding	Weighted Average Exercise Price
Beginning Balance	10,485	$ 404.08	7,481	$ 656.05
Granted	127,353	6.38	5,833	83.96
Exercised	—	—	—	—
Forfeited/expired	(26,922)	39.68	(2,829)	410.34
Outstanding at December 31	110,916	$ 35.90	10,485	$ 404.08
Vested at December 31	8,882	$ 293.89	3,531	$ 727.26

For options outstanding and vested at December 31, 2023 and 2022, the weighted average remaining contractual life was 9.18 years and 8.79 years, respectively. There were no option exercises in 2023 or 2022. The total fair value of options that vested in 2023 and 2022 was $614,100, and $1.1 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 common 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:

	2023	2022
Expected dividend yield	0%	0%
Risk-free interest rate	4.16%	2.13%
Expected volatility	152.28%	132.48%
Expected life (in years)	6.19	6.15

The weighted-average fair value of stock options granted in 2023 and 2022 was $6.09 and $76.05, respectively. As of December 31, 2023, the total compensation cost related to all non-vested stock option awards not yet recognized was approximately $1.1 million and is expected to be recognized over the remaining weighted-average life of 3.01 years.

Warrants: Warrants to purchase 2,963 and 679 shares of common stock were outstanding on December 31, 2023 and 2022, respectively. Exercisable warrants were 151,583 and 679,244 on December 31, 2023 and 2022, respectively. As of December 31, 2023, warrants outstanding were exercisable at prices ranging from $3.30 to $189,000 per share and are exercisable over a period ranging from immediately to 4.8 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.

	2023		2022	
(in thousands)	Fair Value	Level 1	Fair Value	Level 1
Marketable securities	—	—	$ 569	$ 569

The fair value of the Company's common stock warrant liability related to the investor warrants issued in the October 2023 and October 2022 public offerings, were calculated using a Monte Carlo valuation model and were 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)	2023
Balance at December 31, 2021	$ —
October 18, 2022, issuance of Series I warrants	18,695
Change in fair value	(11,827)
Balance at December 31, 2022	6,868
Change in fair value	755
Issuance of Common Stock for exercise of Series I warrants	(7,623)
October 17, 2023, issuance of Series J warrants	4,965
Exercise of Series J warrants	(536)
Change in fair value	(1,586)
Balance at December 31, 2023	$ 2,483

Fair values were calculated using the following assumptions:

	2023	2022
Risk-free interest rates, adjusted for continuous compounding	3.84%-4.92%	3.97%
Term (years)	2.78-3.0	6.11
Expected volatility	141.1%-146.4%	145.3%
Dates and probability of future equity raises	various	various

A significant change in the inputs used for the Monte Carlo 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)	2023	2022
Domestic	$ (20,233)	$ (14,551)
Foreign	32	35
Loss before income taxes	$ (20,201)	$ (14,516)

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

(in thousands)	2023	2022
Current:		
United States and state	$ —	$ —
Foreign, net	(8)	(9)
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax expense	$ (8)	$ (9)

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

(in thousands)	2023	2022
Statutory federal income tax benefit	$ 4,242	$ 3,048
State tax benefit, net of federal taxes	531	783
Foreign tax	(1)	(1)
Nondeductible/nontaxable items	(694)	548
Other	(295)	(41)
Valuation allowance (increase) decrease	(3,791)	(4,346)
Total income tax expense	$ (8)	$ (9)

Deferred taxes consist of the following as of December 31:

(in thousands)	2023	2022
Deferred tax assets:		
Noncurrent:		
Accrued leave	$ 25	$ 397
Stock based compensation	285	360
Net operating loss carryforward	48,818	45,405
Other	26	42
Intangibles	2,627	1,786
R&D credit carryforward	531	531
Total deferred tax assets	52,312	48,521
Less: valuation allowance	(52,312)	(48,521)
Total	$ —	$ —

As of December 31, 2023, the Company had federal net operating loss ("NOL") carryforwards of approximately $212.2 million and state NOL carryforwards of $61.7 million. Approximately $119.7 million of federal NOL carryforwards will expire between 2024 and 2037. Pursuant to the Tax Cuts and Jobs Act of 2017, NOLs generated after 2017 of approximately $92.5 million do not expire. The expiration of state NOL carryforwards will vary by jurisdiction. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code. The Company does not have any foreign loss carryovers.

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, 2023 and 2022, the valuation allowance increased by $3.8 million and $4.3 million, respectively. The current year increase was primarily due to the federal and state net operating losses generated.

During 2023 and 2022, 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, 2023 or 2022.

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, 2023 and 2022, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The tax years ended December 31, 2020 through December 31, 2023 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 Irish subsidiary are subject to examination by tax authorities for the tax years ended December 31, 2020 and subsequent years.

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 $34,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease. 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)	2023	2022
Operating lease cost	$ 249	$ 238
Variable lease cost	142	127
Total	**$ 391**	**$ 365**

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)	2023
2024	$ 257
2025	264
2026	272
2027	69
Total lease payments	862
Less: Interest	(102)
Present value of lease liability	**$ 760**

As of December 31, 2023 and 2022, the remaining lease terms were 3.25 and 4.25 years, respectively, and discount rates were 6.25% and 6.25% respectively. For the years ended December 31, 2023, and 2022, the operating cash outflows from the Company's operating lease for office and manufacturing space were $249,000 and $238,000, 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 $268,000 and $185,000 for the years ended December 31, 2023, and 2022, respectively.

Milestone Payment

On December 27, 2022, the Company entered into a license and distribution agreement with SeaStar Medical Holding Corporation, (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of dysregulated immune responses including hyperinflammation on vital organs ("SeaStar"), appointing the Company as the exclusive U.S. distributor to promote, advertise, market, distribute and sell certain products. As a part of this agreement, the Company agreed to pay SeaStar, a milestone payment of $450,000, upon its receipt of a Human Device Exemption (HDE) approval from the U.S. Food and Drug Administration's (FDA). This payment is due on the later to occur of 30 days after achievement of the milestone event or April 1, 2024. As of December 31, 2023, the Company concluded it was probable HDE approval would be obtained and recorded a liability of $450,000 on the consolidated balance sheet. On February 22, 2024, SeaStar obtained HDE approval.

Note 11—Related Party Transactions

There were no related party transactions requiring disclosure during the year ended December 31, 2023, and 2022.

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, 2023, 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 not effective at a reasonable assurance level as of December 31, 2023. The Certifying Officers based their conclusion on the fact that the Company has identified two material weaknesses in controls over financial reporting, as detailed in this Annual Report on Form 10-K. In light of this fact, management expects to perform additional analyses, reconciliations, and remediations.

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, 2023, 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. As reported herein, we identified two material weaknesses that existed at December 31, 2023. Based on this conclusion, management has concluded that our internal control over financial reporting was ineffective as of December 31, 2023.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

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.

Material Weakness in Internal Control Over Financial Reporting

The Company's management and audit committee of the board of directors have concluded that the fact that the Company did not design appropriate controls resulting from insufficient headcount to fully ensure adequate segregation of duties relating to the accounting and financial reporting function and the information technology function. Additionally, the company did not prepare and retain contemporaneous documentation to evidence the implementation and operation of controls, including controls related to the review of balance sheet reconciliations, the preparation and recording of journal entries, the review of period end financial reporting checklists and controls over user access.

Remediation Plans

We intend to evaluate measures to remediate the identified material weaknesses. The Company plans to continue to assess its internal controls and procedures and take further action as necessary or appropriate to address the material weaknesses. We will not be able to fully remediate these material weaknesses until steps have been completed and have been operating effectively for a sufficient period of time.

The actions that we intend to take are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we decide to take will fully remediate the material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate further action.

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, 2023, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, as a result of the identified material weaknesses, changes in our internal control over financial reporting will occur.

Item 9B. Other Information.

None of the Company's directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the Company's three months ended December 31, 2023, as such terms are defined under Item 408(a) of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors and Executive Officers

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

Name	Age	Position(s)	Director Class – Term Ending
Nestor Jaramillo, Jr.	66	President & Chief Executive Officer; Director	Class I – 2026
Robert B. Scott	44	Chief Financial Officer	N/A
Neil P. Ayotte	61	Senior Vice President, General Counsel and Chief Compliance Officer	N/A
John L. Erb	75	Chairman of the Board; Director	Class III – 2025
Maria Rosa Costanzo	69	Director	Class II – 2024
Archelle Georgiou, M.D.	61	Director	Class II – 2024
Michael McCormick	62	Director	Class I – 2026
David McDonald	63	Director	Class I – 2026
Gregory D. Waller	74	Director	Class III – 2025

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

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

Background and Qualifications

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

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

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

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

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

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

John L. Erb has served as a director of the Company since September 2012 and as chairman of our Board since October 2012. Previously, Mr. Erb served as president and chief executive officer from November 2015 to January 2021. He was executive chairman of the board (during 2007) and chief executive officer (from 2001 to 2006) of the previous owner of the Aquadex™ system, which was also known as CHF Solutions, Inc., a medical device company involved in the development, manufacturing and distribution of devices to treat congestive heart failure. Mr. Erb previously served as chief executive officer (from 2007 to 2020) of NuAx, Inc. (formerly Cardia Access, Inc.), a medical device company involved in developing new devices for the treatment of heart disease; president and chief executive officer of IntraTherapeutics, Inc., a medical device company involved in the development, manufacturing and distribution of peripheral vascular stents, from 1997 to 2001; and in various positions, including as vice president of worldwide operations at Schneider, a division of Pfizer, Inc., from 1991 to 1997. Mr. Erb's prior board experience includes service as a director of SenoRx, Inc., (a Nasdaq listed company), from December 2001 to July 2010; service as a director of CryoCath Technologies Inc., (a publicly traded Canadian company), from October 2000 to December 2008; and service as director of Vascular Solutions, Inc., (a Nasdaq listed company) from 2002 to 2019, where he also served as chairman of the Board (from 2011 to 2017) and chairman of the compensation and nominating and corporate governance committees. Mr. Erb served as a director and chief executive officer of NeuroMedic, Inc., a private company, from 2010 to 2020, when NeuroMedic was acquired by ReCor Medical, Inc. Mr. Erb currently serves as executive chairman of CorRen Medical, Inc. (formerly of CRS Teknologies, Inc.), a private company whose primary business is the development of diagnostic and therapeutic products to treat cardiorenal syndrome ("CorRen"); formerly served as chairman of the board of Osprey Medical, Inc., a public ASX company dedicated to improving heart imaging procedures, ; serves as chairman of the board for IR Medtek, a private company developing oncology products; and formerly served as a director of Miromatrix (Nasdaq: MIRO), Miromatrix, which was acquired by United Therapeutics in 2023. Mr. Erb also serves as a director of Lymphatica Medtech, SA, a private Swiss medical device company focused on lymphatic disease. Mr. Erb received a B.A. in business administration, with a concentration in finance, from California State University, Fullerton.

With over 50 years of experience in the medical device industry, including 20 years of experience serving as chief executive officer of medical device companies, Mr. Erb brings to our Board valuable business, management and leadership experience, as well as a deep understanding of the challenges presented in growing a medical device company. In addition, his role on the boards of Osprey Medical, Vascular Solutions, SenoRx, Miromatrix and CryoCath Technologies has provided him with other public company board experience. Having managed significant operations of a multi-national medical device company, Mr. Erb also contributes valuable private company operational experience.

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

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

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

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

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

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

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

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

Gregory D. Waller has served as a director of the Company since August 2011. Mr. Waller also serves on the board of directors of Arcadia Bioscience, Inc., a publicly traded company (and as chairman of the audit committee and a member of the compensation committee). Until April 2015, Mr. Waller was chief financial officer of Ulthera Corporation, a privately held company that sells an ultrasound device used for non-invasive brow lifts, which was sold to Merz North America in July 2014. From March 2006 to April 2011, Mr. Waller was chief financial officer of Universal Building Products, Inc., a manufacturer of concrete construction accessories. Mr. Waller served as vice president of finance, chief financial officer, and treasurer of Sybron Dental Specialties, Inc., a manufacturer and marketer of consumable dental products, from August 1993 until his retirement in May 2005, and was formerly vice president and treasurer of Kerr, Ormco Corporation, and Metrex. Mr. Waller joined Ormco in December 1980 as vice president and controller and served as vice president of Kerr European Operations from July 1989 to August 1993. Mr. Waller received an M.B.A. with a concentration in accounting from California State University, Fullerton. His prior board service includes service as a director for the following companies: Alsius Corporation, a publicly traded company (chairman of the audit committee and a member of the compensation committee), from June 2007 until its acquisition by Zoll Medical Corporation in September 2009; Biolase Technology, Inc., a publicly traded company (chairman of the audit committee), from October 2009 to August 2010; Cardiogenesis Corporation, a publicly traded company (chairman of the audit committee), from April 2007 until its acquisition by Cryolife in May 2011; Clarient, Inc., a publicly traded company that was acquired by General Electric Company in December 2010 (chairman of the audit committee and a member of the compensation and corporate governance committees), from December 2006 to December 2010; Endologix Corporation, a publicly traded company (chairman of the audit committee and member of the nominating and governance committee), from November 2003 until its reorganization in October 2020 and SenoRx, a publicly traded company that was acquired by C.R. Bard, Inc. in July 2010 (chairman of the audit committee), from May 2006 to July 2010.

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

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

Audit Committee

Our Board has a standing Audit Committee consisting of Mike McCormick, Dave McDonald, and Greg Waller. Our Board has determined that each Audit Committee member has sufficient knowledge in reading and understanding financial statements to serve on the committee. Our Board has further determined that Mr. Waller qualifies as an "audit committee financial expert" in accordance with SEC rules and is independent in accordance with Nasdaq listing rules. The designation of an "audit committee financial expert" does not impose upon him any duties, obligations or liabilities that are greater than those which are generally imposed on him as a member of the committee and the Board, and such designation does not affect the duties, obligations or liabilities of any other member of the committee or the Board.

Code of Conduct

The Board has adopted a Code of Business Conduct and Ethics (the "***Code of Conduct***"), which sets out basic principles to guide the actions and decisions of our employees, directors and officers, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Conduct addresses, among other things, ethical principles, insider trading, conflicts of interest, compliance with laws and confidentiality. The Code of Conduct is posted on our website at https://ir.nuwellis.com/corporate-governance. Any amendments to the Code of Conduct, or any waivers that are required to be disclosed by the rules of either the SEC or Nasdaq, will be posted on our website under the "Investors – Corporate Governance" tab.

Item 11. Executive Compensation.

Director Compensation

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

2023 Director Compensation Table

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

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

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

(1) This amount reflects stock options granted under the 2013 Directors' Plan on May 19, 2023. The amounts reported represent the grant date fair value of the stock options. Valuation assumptions used in determining the grant date fair value are included in Note 5 to the consolidated financial statements for the year ended December 31, 2023, which are included in this Annual Report on Form 10-K. The grant date fair value per share of the stock options granted on May 19, 2023 to all directors was approximately $2.73 per share.
(2) Dr. Costanzo elected not to receive any equity compensation for her role as a director.
(3) As of December 31, 2023, each non-employee director had the following number of shares underlying outstanding options (both vested and unvested): Dr. Costanzo 0; Mr. Erb 2,391, Dr. Georgiou 0; Mr. McCormick 0, Mr. McDonald 0, and Mr. Waller 2,408.
(4) Mr. Brandt resigned from the Board effective January 16, 2023.
(5) Dr. Georgiou was appointed to the Board effective November 1, 2023.
(6) Mr. McCormick was appointed to the Board effective June 1, 2023.
(7) Mr. McDonald was appointed to the Board effective November 1, 2023.
(8) Mr. Salveson resigned from the Board effective October 31, 2023.
(9) Mr. Watson resigned from the Board effective June 2, 2023.

Our Non-Employee Director Compensation Policy, which was adopted in May 2019, (and amended in August 2021 upon the retirement of Mr. Erb, and further amended and restated in January of 2023 following FW Cook's market assessment of non-employee director compensations across our peer group) provides for annual cash and equity compensation. Each non-employee director receives annual cash compensation of $45,000, the lead independent director receives an additional $10,000 per year and the Chair of the Board receives and additional $15,000 per year. Directors also receive annual cash compensation for service on committees. For the Audit Committee, the chair now receives $15,000 per year and each other member receives $7,500 per year. For the Compensation and the Nominating and Corporate Governance Committees, the chair receives $10,000 per year and each other member receives $5,000 per year. Cash compensation is paid in four quarterly installments following completion of the applicable quarter.

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

Named Executive Officer Compensation Tables

Summary Compensation Table for 2023 and 2022

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

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1][2]	Non-equity Incentive Plan Compensation ($)	All Other Compensation ($)[3]	Total ($)
Nestor Jaramillo, Jr.						
President & Chief Executive Officer	2023	420,582	168,891	—	17,130	606,603
	2022	412,337	86,238	199,117	17,022	714,714
Robert B. Scott						
Chief Financial Officer[4]	2023	243,157	38,811	—	9,442	291,410
	2022	—	—	—	—	—
Lynn L. Blake						
Former Chief Financial Officer[5]	2023	248,681	99,982	—	11,040	359,703
	2022	65,417	—	26,744	642	92,803
Neil P. Ayotte SVP,						
General Counsel & Chief Compliance Officer	2023	326,457	63,945	—	16,083	406,485
	2022	289,848	22,434	92,165	9,104	413,551

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

Narrative Discussion of Summary Compensation Table for 2023

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

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

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

Equity Compensation. In 2022, Mr. Jaramillo received an option to purchase 1,011 shares of common stock at an exercise price of $94 per share effective March 3, 2022, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. Mr. Ayotte received an option to purchase 263 shares of common stock at an exercise price of $94 per share effective March 3, 2022, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. In 2023, pursuant to a first amendment to the Blake Offer Letter, Ms. Blake received an option to purchase 12,417 shares of common stock at an exercise price of $8.36 per share effective January 6, 2023, with vesting as follows: 25% of the options will vest on October 19, 2023 with the remaining shares vesting in 36 equal consecutive monthly increments thereafter, so that all shares will be vested on October 19, 2026, all of which were forfeited upon Ms. Blake's resignation on September 1, 2023. Mr. Ayotte received an option to purchase 8,640 shares of common stock at an exercise price of $7.72 per share effective March 3, 2023, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. Mr. Jaramillo received options to purchase 8,954 and 13,866 shares of common stock, respectively, each at an exercise price of $7.72 per share effective March 3, 2023, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date. Mr. Scott received options to purchase 18,643 shares of common stock, at an exercise price of $1.79 per share effective September 2, 2023, with vesting as follows: 25% of the shares vest on the one-year anniversary of the grant date and the remaining shares vest in 36 equal consecutive monthly increments thereafter, so that all of the shares will be vested on the four-year anniversary of the grant date.

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

The earned bonus was based on the achievement of corporate performance objectives established and weighted by the Compensation Committee, in consultation with our chief executive officer, and primarily related to our annual revenue, the number of clinical sites active under the REVERSE-HF clinical trial and selected product development milestones related to the Company's dedicated pediatric dialysis device, which is under development. The Compensation Committee assessed our achievement of the corporate objectives at 2023 year-end, however, no payout was authorized for any named executive officer or any other employee in light of the Company's liquidity.

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

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

Offer Letter – Ms. Blake

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

Offer Letter – Mr. Scott

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

Offer Letter – Mr. Ayotte

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

Outstanding Equity Awards at Fiscal Year-End 2023

The following table sets forth certain information concerning equity awards held by our named executive officers that were outstanding as of December 31, 2023. There were no stock awards issued in 2023.

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

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

Potential Payments Upon Termination or Change in Control

Equity Compensation Plans

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

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

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

Change in Control Agreements

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

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

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

In addition to the payments described above, each change in control agreement provides that if a change in control occurs while the officer is actively employed by the Company and during the term of the agreement, such change in control will cause the immediate acceleration of the vesting of 100% of any unvested portion of any stock option awards held by the officer on the effective date of such change in control.

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

Employment Agreement – Mr. Jaramillo

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

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

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

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

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

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

Upon termination of Mr. Jaramillo's employment, Mr. Jaramillo may be entitled to certain payments and benefits, depending on the reason for his termination. In the event Mr. Jaramillo resigns his employment without good reason, the Company terminates Mr. Jaramillo's employment for cause, or Mr. Jaramillo's employment terminates as a result of his death or disability, Mr. Jaramillo is entitled to receive the Unconditional Entitlements, but not the Conditional Benefits (each as defined below). In the event Mr. Jaramillo resigns with good reason or the Company terminates Mr. Jaramillo's employment for a reason other than cause, Mr. Jaramillo is entitled to receive the Unconditional Entitlements, as well as the Conditional Benefits, provided that Mr. Jaramillo signs and delivers to the Company, and does not revoke, a general release of claims in favor of the Company and certain related parties.

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

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

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

The following table sets forth information regarding the beneficial ownership (as defined in Rule 13d-3 of the Exchange Act) of our common stock as of February 29, 2024 by (i) each of the directors and named executive officers, (ii) all of the directors and executive officers as a group, and (iii) to our knowledge, beneficial owners of more than 5% of our common stock. As of March 1, 2024, there were 6,801,443 shares of our common stock outstanding. Unless otherwise indicated and subject to applicable community property laws, each owner has sole voting and investment powers with respect to the securities listed below.

Name of Beneficial Owner	Number of Shares	Right to Acquire[1]	Total	Aggregate Percent of Class[2]
John L. Erb	4	6,219[3]	6,223	*
Michael McCormick	—	17,364	17,364	*
Maria Rosa Costanzo, M.D.	—	—	—	—
Archelle Georgiou, M.D.	—	4,736	4,736	*
Gregory D. Waller	—	2,230[4]	2,230	*
David McDonald	—	4,736	4,736	
Robert B. Scott	—	127[5]	127	*
Nestor Jaramillo, Jr.	4,098	2,759[6]	6,857	*
Neil P. Ayotte	—	791[7]	791	*
Lynn Blake	100	—	100	*
All current directors and executive officers as a group (9 persons)	4,202	38,962 [8]	43,164	* %

* Less than one percent.

(1) Except as otherwise described below, amounts reflect the number of shares that such holder could acquire through (i) the exercise of outstanding stock options, (ii) the vesting/settlement of outstanding RSUs, (iii) the exercise of outstanding warrants to purchase common stock, and (iv) the conversion of outstanding Series F Preferred Stock, in each case within 60 days after February 29, 2024.

(2) Based on 6,801,443 shares outstanding as of March 1, 2024.

(3) Consists of (i) 2,213 shares issuable upon the exercise of outstanding stock options, (ii) 6 shares issuable upon the exercise of outstanding warrants to purchase common stock, and (iii) 4,000 shares issuable upon conversion of outstanding shares of Series F Convertible Preferred Stock (assuming all 127 shares of Series F Convertible Preferred Stock held by Mr. Erb are converted at once and rounded up to the nearest whole share).

(4) Consists of 2,230 shares issuable upon the exercise of outstanding stock options.

(5) Consists of 127 shares issuable upon the exercise of outstanding stock options.

(6) Consists of 2,759 shares issuable upon the exercise of outstanding stock options.

(7) Consists of 791 shares issuable upon the exercise of outstanding stock options.

(8) Consists of (i) 0 shares issuable upon the vesting/settlement of outstanding RSUs, (ii) 34,956 shares issuable upon the exercise of outstanding stock options, (iii) 6 shares issuable upon the exercise of outstanding warrants to purchase common stock, and (iv) 4,000 shares issuable upon conversion of outstanding shares of Series F Convertible Preferred Stock (assuming all shares Series F Convertible Preferred Stock are converted at once and rounded up to the nearest whole shares).

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2023, concerning our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	104,684	(1)	$ 29.52	1,025	(2)
Equity compensation plans not approved by security holders	6,232	(3)	$ 142.94	40,846	(4)
Total	**110,916**		**$ 35.90**	**41,871**	

(1) Consists of shares of our common stock that may be issued pursuant to outstanding stock options under the Second Amended and Restated 2011 Equity Incentive Plan (the "2011 Plan"), the 2017 Equity Incentive Plan (the "2017 Plan") and the 2013 Directors' Plan. The 2013 Non-Employee Directors' Equity Incentive Plan (the "2013 Directors' Plan") expired in May 2023.

(2) Consists of 1,025 shares of our common stock remaining available for future issuance under the 2017 Plan and 0 shares of our common stock remaining available for future issuance under the 2013 Directors' Plan. No additional awards may be issued under the 2002 Stock Plan or the 2011 Equity Incentive Plan. The 2017 Equity Incentive Plan contains an "evergreen" provision, pursuant to which the number of shares available for issuance under the plan automatically adjusts by a percentage of the number of fully diluted shares outstanding. Specifically, pursuant to the 2017 Equity Incentive Plan, the share reserve under the plan will automatically increase on January 1st of each year, for a period of not more than ten years, commencing on January 1, 2018 and ending on (and including) January 1, 2027, to an amount equal to 17% of the fully diluted shares outstanding on December 31st of the preceding calendar year; provided that the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares than would otherwise occur. Prior to its expiration in May 2023 and pursuant to the terms of the 2013 Directors' Plan, the share reserve under the plan automatically increased on January 1st of each year, for a period of not more than ten years, commencing on January 1, 2014 and ending on (and including) January 1, 2023, by an amount equal to 2% of the fully diluted shares outstanding on December 31st of the preceding calendar year; provided that the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in the share reserve for such year or that the increase in the share reserve for such year will be a lesser number of shares than would otherwise occur.

(3) Consists of shares of our common stock that may be issued pursuant to outstanding stock options under the New Hire Plan. The Board approved the New Hire Plan in July 2013. The New Hire Plan was superseded by our 2021 Inducement Plan in May 2021. The New Hire Plan provided for the grant of the following awards: options not intended to qualify as "incentive stock options" under Section 422 of the Code, restricted stock awards, RSU awards, stock appreciation rights and other stock awards. Eligible award recipients are individuals entering into employment with the Company who were not previously employees or directors of the Company or following a *bona fide* period of non-employment. All awards constituted inducements material to such individuals entering into employment with the Company within the meaning of the Nasdaq listing rules, and all awards must be granted either by the Compensation Committee or a majority of the Company's independent directors. Promptly following the grant of an award under the New Hire Plan, the Company (i) issued a press release disclosing the material terms of the award and (ii) notified Nasdaq that it granted such award in reliance on the "inducement grant exemption" from Nasdaq's stockholder approval requirements for equity compensation plans. As of May 2021, we are no longer issuing awards under the New Hire Plan.

(4) Consists of shares of our common stock that may be issued pursuant to outstanding stock options under the Company's 2021 Inducement Plan. The Board approved the 2021 Inducement Plan in May 2021. The 2021 Inducement Plan provides for the grant of the following awards: options not intended to qualify as "incentive stock options" under Section 422 of the Code, restricted stock awards, RSU awards, stock appreciation rights, performance stock awards, performance cash awards, and other stock awards. Eligible award recipients are individuals entering into employment with the Company who were not previously employees or directors of the Company or following a *bona fide* period of non-employment. All awards must constitute inducements material to such individuals entering into employment with the Company within the meaning of the Nasdaq listing rules, and all awards must be granted either by the Compensation Committee or a majority of the Company's independent directors. Promptly following the grant of an award under the 2021 Inducement Plan, the Company must (i) issue a press release disclosing the material terms of the award and (ii) notify Nasdaq that it granted such award in reliance on the "inducement grant exemption" from Nasdaq's stockholder approval requirements for equity compensation plans.

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

Director Independence

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

Our Board has affirmatively determined, after considering all of the relevant facts and circumstances, that Mr. Brandt, who retired from the Board in January 2023, Mr. Salveson, who resigned from the Board in October 2023, and Mr. Watson, who resigned from the Board in June 2023, were independent directors while serving as a member of the Board, and Dr. Costanzo, Dr. Georgiou, Mr. McCormick, Mr. McDonald, and Mr. Waller, are independent directors under the applicable rules of Nasdaq, which consists of all of our directors except for Mr. Erb, former chief executive officer and president and current Chairman of the Board, and Mr. Jaramillo, our President and Chief Executive Officer. Mr. McCormick serves as our lead independent director. Each member of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee is independent under Nasdaq rules. In addition, our Board has affirmatively determined that the members of the Audit Committee and Compensation Committee qualify as independent in accordance with the additional independence rules established by the SEC and Nasdaq.

Certain Relationships and Related Person Transactions

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

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

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

Item 14. Principal Accountant Fees and Services.

AUDIT COMMITTEE MATTERS

Pre-Approval Policies and Procedures

The Audit Committee has adopted an auditor services pre-approval policy applicable to services performed for the Company by its independent registered public accounting firm. In accordance with this policy, the Audit Committee's practice is to assess the permissibility of and pre-approve all audit, audit-related and non-audit services to be provided by the independent registered public accounting firm during the year. The Audit Committee may form and delegate authority to subcommittees consisting of one or more members when appropriate, including the authority to grant pre-approvals of audit and permissible audit-related and non-audit services. Any pre-approvals granted pursuant to delegated authority must be reported to the committee at its next regular meeting. The Audit Committee's pre-approval policy is in the Audit Committee Charter, which is available on our website at http://ir.nuwellis.com/corporate-governance.

The Audit Committee has determined that the provision of the non-audit services described in the table below was compatible with maintaining the independence of our independent registered public accounting firm. The Audit Committee reviews each non-audit service to be provided and assesses the impact of the service on the auditor's independence.

Independent Registered Public Accounting Firm Fees

Baker Tilly served as our independent registered public accounting firm for the years ended December 31, 2023 and December 31, 2022. The following table sets forth the fees we incurred for audit and other services provided by Baker Tilly in 2023 and 2022. 100% of such services described below were pre-approved in conformity with the Audit Committee's pre-approval policies and procedures described above.

	2022 ($)	2023 ($)
Audit Fees[1]	333,755	378,500
Audit-Related Fees[2]	122,500	279,025
Tax Fees[3][4]	33,400	32,800
All Other Fees	—	—
Total	**489,655**	**690,325**

(1) Audit fees in 2023 and 2022 consisted of fees relating to the audit of the Company's annual consolidated financial statements included in our Annual Report on Form 10-K and the review of interim condensed consolidated financial statements included in the Company's Quarterly Reports on Form 10-Q.

(2) Audit-Related fees consisted of reviews of the Company's registration statements, consents and the completion of comfort letter procedures associated with the Company's securities offerings.

(3) Tax fees in 2023 and 2022 consisted of fees for tax compliance, and tax planning services. Such fees primarily related to federal and state tax compliance and planning.

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	
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
3.9	Third Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2
3.10	Amendment to Third Amended and Restated Bylaws	8-K	001-35312	October 5, 2022	3.1
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
3.14	Certificate of Designation of Preferences, Rights and Limitations of Series J Convertible Preferred Stock	8-K	001-35312	October 17, 2023	3.1
4.1	Form of Warrant to purchase shares of common stock	S-1/A	333-221010	November 17, 2017	4.9
4.2	Form of Series 1 and Series 2 Warrant to Purchase Shares of Common Stock	S-1/A	333-209102	February 25, 2019	4.10
4.3	Common Stock Purchase Warrant, dated May 30, 2019, between the Company and Redington, Inc.	10-Q	001-35312	August 8, 2019	4.1

4.4	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated October 23, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	October 23,2019	4.1
4.5	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.1
4.6	Form of common stock Pre-Funded Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.2
4.7	Form of Common Stock Purchase Warrant	S-1/A	333-235385	January 23, 2020	4.15
4.8	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated March 19, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 20, 2020	4.1
4.9	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated March 30, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 30, 2020	4.1
4.10	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated May 1, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	May 4, 2020	4.1

4.11	Form of Warrant to Purchase Shares of Common Stock	S-1/A	333-24145	August 17, 2020	4.19	
4.12	Warrant to purchase shares of Common Stock	S-1/A	333-267368	October 13, 2022	4.20	
4.13	Form of Warrant to purchase shares of common stock	S-1/A	333-274610	September 29, 2023	4.13	
4.14	Description of Securities					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
10.10	Fifth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	January 18, 2018	10.1
10.11	Sixth Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2019	10.2
10.12	Seventh Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	December 6, 2019	10.1
10.13	Eighth Amendment to New-Hire Equity Incentive Plan†	8-K/A	001-35312	February 25, 2021	10.1
10.14	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.2
10.15	2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.1
10.16	First Amendment to the 2017 Equity Incentive Plan†	14A	001-35312	September 11, 2020	App. A
10.17	Second Amendment to the 2017 Equity Incentive Plan†	10-K	001-35312	March 3, 2023	10.17
10.18	Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.2
10.19	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.3
10.20	Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.1
10.21	First Amendment to the 2021 Inducement Plan†	8-K	001-35312	April 21, 2022	10.1
10.22	Second Amendment to the 2021 Inducement Plan †	8-K	001-35312	March 1, 2023	10.1

10.23	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.2
10.24	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1
10.25	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16
10.26	Non-Employee Director Compensation Policy (effective August 18, 2021)†	10-Q	001-35312	November 10, 2021	10.2
10.27	Non-Employee Director Compensation Policy (effective January 1, 2023) †	10-K	001-35312	March 3, 2023	10.27
10.28	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18
10.29	Second Amendment to Lease, dated as of April 20, 2015, by and between the Company and Capital Partners Industrial Fund I, LLLP dba Prairie Crossroads Business Center	8-K	001-35312	April 23, 2015	10.1
10.30	Third Amendment to Lease, dated as of August 3, 2018, by and between the Company and Capital Partners Industrial Fund I, LLLP	10-Q	001-35312	November 7, 2018	10.2
10.31	Fourth Amendment to Lease, dated as of November 18, 2021, by and between the Company and Capital Partners Industrial Fund I, LLLP	8-K	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
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

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
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
10.63	License and Distribution Agreement with SeaStar Medical Holding Corporation, dated as of December 27, 2022+	10-K	001-35312	March 3, 2023	10.63
10.64	At The Market Offering Agreement, dated as of March 2, 2023, by and between the Company and Ladenburg Thalmann & Co. Inc.	10-K	001-35312	March 3, 2023	1.1

10.65+	Supply and Collaboration Agreement dated as of June 19, 2023 by and between the Company and DaVita Inc.	8-K	001-35312	June 21, 2023	10.1	
10.66	Registration Rights Agreement dated as of June 19, 2023 by and between the Company and DaVita Inc.	8-K	001-35312	June 21, 2023	10.2	
10.67+	DaVita Inc. Common Stock Warrant Agreement	8-K	001-35312	June 21, 2023	4.1	
10.68†	Transition Agreement dated August 4, 2023 by and between Nuwellis, Inc. and Lynn Blake	8-K	001-35312	August 8, 2023	10.1	
10.69†	Offer Letter by and between Nuwellis, Inc. and Robert B. Scott, effective as of September 2, 2023	8-K	001-35312	August 18, 2023	10.1	
10.70	Placement Agency Agreement dated as of October 12, 2023, by and between Nuwellis, Inc., Lake Street Capital Markets, LLC and Maxim Group LLC	8-K	001-35312	October 17, 2023	1.1	
10.71	Form of Securities Purchase Agreement	S-1/A	333-274610	September 29, 2023	10.69	
10.72	Form of Warrant Agency Agreement	8-K	001-35312	October 17, 2023	4.2	
10.73	Consulting Agreement dated August 4, 2023 by and between Nuwellis, Inc. and Lunn Blake†	S-1/A	333-274610	September 29, 2023	10.68	
21	List of Subsidiaries					X
23.1	Consent of Baker Tilly US, LLP					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
97	Policy for the Recovery of Erroneously Award Compensation	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 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, Warrant and Supply 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. Copies of the unredacted License and Distribution Agreement, Warrant and Supply 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 11, 2024

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 Robert Scott 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 11, 2024
/S/ ROBERT SCOTT Robert Scott	Chief Financial Officer (principal financial and accounting officer)	March 11, 2024
/S/ JOHN L. ERB John L. Erb	Chairman of the Board and Director	March 11, 2024
/S/ MARIA ROSA COSTANZO Maria Rosa Costanzo M.D.	Director	March 11, 2024
/S/ DAVE McDONALD David McDonald	Director	March 11, 2024
/S/ GREGORY D. WALLER Gregory D. Waller	Director	March 11, 2024
/S/ MIKE McCORMICK Mike McCormick	Director	March 11, 2024
/S/ ARCHELLE GEORGIOU, M.D. Archelle Georgiou, M.D.	Director	March 11, 2024