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, 2021

☐ **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. ☐

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, 2021, 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, 2021 closing sale price of $4.20 per share) was approximately $27.4 million.

The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of February 25, 2022 was 10,537,606 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the 2022 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 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 FlexFlow® and the Aquadex SmartFlow® systems (collectively the "Aquadex System"). The Aquadex SmartFlow® system is indicated for temporary (up to eight hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20kg or more whose fluid overload is unresponsive to medical management, including diuretics.

Fluid Overload

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

The signs and symptoms of fluid overload are not always the same in each patient and may vary. However, possible signs and symptoms of fluid overload include pulmonary edema/pleural effusion, peripheral edema, anasarca (swelling of the skin) ascites, jugular vein distention and dyspnea. Medical conditions or diseases where excess fluid accumulates in the body are heart failure, kidney failure, nephrotic syndrome, cirrhosis, or burn injuries/trauma. Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery. The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight and edema), blood chemistry, electrocardiogram (ECG or EKG), glomerular filtration rate (GFR), liver enzymes, and urinalysis, or serum/urine sodium test. Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema[1] and is a leading cause of readmissions with patients suffering from heart failure and patients following cardiac surgery.

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

Treatments for Fluid Overload

Diuretics

Treatment for fluid overload has traditionally been achieved through use of loop diuretics which may be accompanied by use of other categories of medications, such as ACE inhibitors, beta-blockers, and inotropic drugs. Although diuretics are the mainstay of treatment for congestion or fluid overload, no randomized trials have shown the effects of diuretics on mortality in chronic heart failure patients. Furthermore, appropriate titration of diuretics, specifically in the heart failure population, is unclear. Increasing concern exists that diuretics, particularly at high doses, may be deleterious in the inpatient setting. In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.[4] Also, long term use of diuretics has been associated with kidney damage.[5] Approximately 40% of heart failure patients have poor diuretic response.[6] This poor response is possibly due to noncompliance or high intake of salt, poor drug absorption, insufficient kidney response to drug, and reduced diuretic secretion.[7] Despite treatment with loop diuretics, patients are frequently hospitalized and treated for recurrent symptoms and signs of fluid overload. Among more than 50,000 patients enrolled in the Acute Decompensated Heart Failure National Registry ("ADHERE") study, only 33% lost ≥ 2.27 kg (5 lbs.), and 16% gained weight during hospitalization.[8]

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[1] Stein, Aet. al. Critical Care, 2012:16:R99
[2] Ronco C, Costanzo MR, Bellomo R, et al. (2010) Fluid Overload Diagnosis and Management. Basel, Switzerland: Karger.
[3] Ellison DH. Diuretic therapy and resistance in congestive heart failure. Cardiology.2001;96:132-143.
[4] Kamath SA. The role of ultrafiltration in patients with decompensated heart failure. Int J of Nephrol.2011.
[5] Felker MG. Diuretics and ultrafiltration in acute decompensated heart failure J Am Coll Cardiol 2012 Jun 12;59(24):2145-53.
[6] Testani JM, Hanberg JS, Cheng S, et al. Rapid and highly accurate prediction of poor loop diuretic natriuretic response in patients with heart failure. Circ Heart Fail. 2016 Jan;9(1):e002370.
[7] Hoorn EJ and Ellison DH. Diuretic Resistance. Am J Kidney Dis. 2017;69(1):136-142.
[8] Costanzo MR, Ronco C, Abrahman WT, et al. Extracorporeal ultrafiltration for fluid overload in heart failure. J Am Coll Cardiol. 2017;69(19):2428-2445.

Nearly one-half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.[9] Regardless of diuretic strategy, 42% of acutely decompensated heart failure subjects in the DOSE (Diuretic Optimization Strategies Evaluation) trial reached the composite endpoint of death, rehospitalization, or emergency department visit at 60 days.[10] There is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.[11] Therefore, an alternative therapy to help stabilize or improve patient care is needed.

Ultrafiltration.

Ultrafiltration, or aquapheresis, is an alternative therapy to diuretics for fluid removal in patients with volume overload. Ultrafiltration has been a well-documented technique in the treatment of fluid overload in heart failure patients for over 20 years.[12] Ultrafiltration is a safe and effective alternative therapy to remove extra fluid and salt by gently filtering blood through an ultrafiltration system. With ultrafiltration, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The use of ultrafiltration therapy in subgroups of patients, such as heart failure and post-cardiac surgery, has demonstrated clinical benefits in treating fluid overload signs and symptoms. In addition to the clinical benefits of ultrafiltration, the therapy provides economic advantages. One hospital cost analysis demonstrated a total cost savings of $3,975, or 14.4%, per patient when using ultrafiltration as compared to diuretic therapy over 90 days.[13]

The Aquadex System

The Aquadex System is designed and clinically proven to simply, safely, and precisely remove excess fluid (primarily excess salt and water) from patients suffering from fluid overload who have failed diuretic therapy. With the Aquadex System, medical practitioners can specify and control the amount of fluid to be extracted at a safe, predictable, and effective rate. The Aquadex System has been shown to have no clinically significant impact on electrolyte balance, blood pressure or heart rate.[14] Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex System may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies.

Benefits of the Aquadex System

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

- Provides complete control over rate and total volume of fluid removed by allowing a medical practitioner to specify the amount of fluid to be removed from each individual patient;
- Can be performed via peripheral or central venous access;
- Removes isotonic fluid (extracts sodium while sparing potassium and magnesium);[15]
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;[16]
- Provides highly automated operation with only one setting required to begin therapy;
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up;
- Has a built-in console that guides the medical practitioner through the setup and operational process; and
- Decreased hospital readmissions and duration resulting in cost savings at 90 days.[17] [18]

[9] Gheorghiade M, Filippatos G. Reassessing treatment of acute heart failure syndromes: the ADHERE registry. Eur Heart J Suppl. 2005; 7:B13–19.
[10] Felker GM, Lee KL, Bull DA, et al. Diuretic strategies in patients with acute decompensated heart failure. N Engl J Med. 2011; 364:797–805.
[11] Costanzo MR, Guglin ME, Saltzberg MT, et al. Ultrafiltration versus intravenous diuretics for patients hospitalized for acute decompensated heart failure. J Am Coll Cardiol. 2007; 49(6):675-683.
[12] Agostoni PG, Marenzi GC, Pepi M, et al. Isolated ultrafiltration in moderate congestive heart failure. J Am Coll Cardiol. 1993; 21(2):424-431.
[13] Costanza MR, et. al. Ultrafiltration vs. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Value Health. 2018; 21 (Suppl 1):S167.
[14] SAFE Trial: Jaski BE, et al. J Card Fail. 2003 Jun; 9(3): 227-231; RAPID Trial: Bart BA, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2043-2046.
[15] Ali SS, et al. Congest Heart Fail. 2009; 15(1):1-4.
[16] Marenzi G, et al. J Am Coll Cardiol. 2001 Oct; 38(4): 963-968.
[17] Costanzo MR, et al. J Am Coll Cardiol. 2005 Dec 6; 46(11): 2047-2051.
[18] Costanzo MR, et al. Ultrafiltration v. Diuretics for the Treatment of Fluid Overload in Patients with Heart Failure: A Hospital Cost Analysis. Poster presented at the ISPOR meeting, May 23, 2018, Baltimore, MD, USA.

Components of the Aquadex System

The Aquadex System consists of:

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

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

Our Market Opportunity

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

Critical Care

Patients suffer from fluid overload in connection with a variety of critical care procedures and treatments, including cardiac surgery, cardiogenic shock, liver and other organ transplants, ventricular assist device ("VAD") implants, extra corporeal membrane oxygenation ("ECMO") therapy, sepsis, liver disease and severe burns. According to the National Center for Health Sciences, over 7.3 million cardiovascular operations are performed each year in the United States, including an estimated 340,000 coronary-artery bypass grafting (CABG) procedures[19], 180,000 valve procedures[20], and 3,000 VAD implants[21]. Cardiac surgery is associated with a degree of fluid overload due to cardiopulmonary bypass. Cardiopulmonary bypass often requires a physician to administer a high volume of pre- and post-operative fluids (e.g., cardiopulmonary bypass pumps prime fluid, fluid used for cardioplegia, other fluids administered to address hypotension or post-operative crystalloid). Fluid overload in post-cardiac surgery can readily occur because surgery can affect the pumping actions of the heart, leading to postoperative hemodynamic instability. The condition often remains symptomless for several days until clinical symptoms become apparent, when treatment is almost always too late and ineffective.[22]

The potential complications (e.g., renal failure, stroke, infection, arrhythmias, or prolonged intubation) are reported to be associated with high mortality, particularly when renal replacement therapy is required. Major complications after cardiac operations are associated with an increased risk for operative death, longer hospital length of stay, and higher rates of discharge to a location other than home.[23] 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.[24] 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.[25]

Heart Failure

Heart failure is one of the leading causes of death in the United States and other developed countries. In fact, approximately 50% of patients who develop heart failure die within five years of diagnosis. Based on data from the National Health and Nutrition Examination Survey conducted by the Centers for Disease Control and Prevention/National Center for Health Statistics from 2011 to 2014, the American Heart Association estimates that 6.5 million people in the United States, age 20 and over, had heart failure[26].

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19 https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/.
20 https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/.
21 Grand View Research. Market Research Report. 2015; 978-1-68038-603-5.
22 Xu J, Shen B, Fang Y, et al. Postoperative fluid overload is a useful predictor of the short-term outcome of renal replacement therapy for acute kidney injury after cardiac surgery. Medicine. 2015;94(33):e1360.
23 Crawford TC, Magruder JT, Grimm JC, et al. Complications after cardiac surgery: All are not created equal. Ann Thorac Surg. 2017;103:32-40.
24 Iribane A, Chang H, Alexander Jh, et al. Readmissions after cardiac surgery: Experience of the national institutes of health/Canadian institutes of health research cardiothoracic surgical trials network. Ann Thorac Surg. 2014;98:1274-80.
25 Iribarne A, et al. Ann Thorac Surg. 2014 Oct; 98(4): 1274-80.
26 Benjamin EJ, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation. 2017;135:00-00. (e378).

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[27]. 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[28]. In addition, approximately 68% of patients are discharged with sub-optimal results.[29] As such, there are over 600,000 heart failure patients in the United States who might benefit from new technologies to treat fluid overload.

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

According to a nationwide study of over 140,000 patients suffering from acute decompensated heart failure, over 38% of patients discharged were still symptomatic and about half of the patients were discharged with less than five pounds lost.[30] This clinical evidence from the ADHERE registry clearly shows patients are discharged too early, while still showing evidence of fluid overload.

As a result of not fully having their fluid imbalance properly addressed prior to discharge from the hospital, patients are frequently being readmitted, with 30-day readmissions of 22% and 6-month readmissions of 44%, while 78% of patients are admitted directly to the emergency department as the first point of care.[31, 32]

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.[33] As the population ages, healthcare expenditures are expected to increase substantially.[34] Therefore, therapies aimed at treating congestion and fluid overload are essential from a patient care and health economic perspective.

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

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

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 [35] and approximately 18,000 receiving cardiac surgery, ECMO therapy, and solid organ transplantation. [36, 37, 38]

Our Strategy

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[27] Benjamin EJ, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation. 2017;135:00-00. (e378).
[28] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69(19): 2428-45.
[29] Testani JM, et al. Circ Heart Failure. 2016;9(1).
[30] ADHERE Scientific Advisory Committee. ADHERE Final Cumulative National Benchmark Report. Mountain View, CA: Scios Inc.; 2006.
[31] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69(19): 2428-2445.
[32] Krumholtz HM et. al. Arch Intern Med. 1997 Jan 13;157(1): 99-104—Ross JS, et al. Circ Heart Fail. 2010 Jan; 3(1): 97-103.
[33] Voigt J, John S, Taylor A, Krucoff M, Reynolds M, Gibson CM. A Reevaluation of the costs of heart failure and its implications for allocation of health resources in the United States. Clin Cardiol. 2014;37(5): 312–321.
[34] Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. 2013;6(3):606-619.
[35] Jayaprasad. Heart Views. 2016 Jul-Sep; 17(3): 92–99.
[36] https://www.cdc.gov/ncbddd/heartdefects/data.html.
[37] Karamlou T, et al. J Thorac Cardiovasc Surg. 2013 Feb;145(2):470-5. doi: 10.1016/j.jtcvs.2012.11.037. Epub 2012 Dec 14.
[38] https://www.organdonor.gov/about/donors/child-infant.html.

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 specialists in 11 sales territories in the United States. We also have distribution agreements in several countries in Europe, South America, 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 eventually the outpatient setting. With the recent U.S. Food and Drug Administration ("FDA") 510(k) clearance for use in pediatric patients weighing 20kg or more, we have expanded our commercialization efforts to treatments for pediatric patients.

Critical Care: In 2018, 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, valve repairs and replacements procedures, VAD implants and other cardiac surgical procedures. In 2019, we realigned our sales force 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[39], ECMO therapy[40], solid organ transplantation[41], and kidney replacement therapy for neonatal patients. In February 2020, the Company received 510(k) clearance of 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 into product development of a dedicated pediatric device to further address the needs of the pediatric population. We are investing in the development of new clinical evidence around use of ultrafiltration in pediatric patients, including the November 2020 launch of the ULTRA-Peds pediatrics registry, a multi-center, single-arm study. We plan to invest in other clinical studies in this patient population.

Heart Failure In-Patients: Heart failure patients suffering from fluid overload may be treated in an inpatient setting, such as a hospital, extended care facility or nursing home. Historically, our commercial efforts have been primarily focused on use of the Aquadex System in the inpatient setting in large hospital accounts. We intend to continue to support our sales efforts on inpatient facilities, leveraging the clinical benefits and economic advantages of using the Aquadex System over diuretic therapy. We are investing in additional clinical evidence supporting the use of ultrafiltration in patients with decompensated heart failure including a multicenter, randomized controlled trial, the REVERSE-HF study, comparing ultrafiltration and IV diuretics.

Heart Failure Out-Patients: Further, we intend to expand the use of the Aquadex System with heart failure patients in the outpatient setting, such as an infusion clinic or hospital outpatient department (e.g., observation unit). On January 1, 2022, the American Medical Association (AMA) granted a new and dedicated Category III Current Procedural Terminology (CPT) code, 0692T, for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver ultrafiltration to adult and pediatric patients weighing more than 20 kilograms. 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.

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

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

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

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

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. We also are collaborating with partners to evaluate 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. As we expand our commercialization efforts in the pediatric market, we are developing a Continuous Renal Replacement Therapy (CRRT) console to address the unmet and specific needs of pediatric patients who do not have functioning kidneys and need kidney replacement therapy for survival. It is estimated that approximately 11,000 newborn babies require neonatal kidney replacement therapy each year in the United States.[42]

Sales and Marketing

As of February 25, 2022, we had 33 full-time employees in sales and marketing. We have 11 sales territories in the United States. Our U.S. sales force includes sales managers, account managers and field clinical specialists who provide training, technical and other support services to our customers. Following the acquisition of the business associated with the Aquadex System (the "Aquadex Business") from Baxter International, Inc. ("Baxter") in August 2016, our direct sales force 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 sales force 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 health care systems and academic hospitals specializing in advanced treatment of chronic heart failure and/or critical care patients. With the 510(k) clearance of the Aquadex SmartFlow® system for pediatric patients weighing over 20 kg, we are also targeting pediatric hospitals. Our largest customer represented 12.3% of our 2021 annual revenue. The loss of this customer would have a material adverse effect on our revenue.

Clinical Experience

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

The UNLOAD trial enrolled 200 patients and showed that average weight and fluid loss were greater in the ultrafiltration group 48 hours following randomization. No differences were noted in symptoms of dyspnea between the groups. In addition, through 90 days of follow-up, the ultrafiltration group experienced fewer re-hospitalizations 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, particularly that trial results were impacted by centers unfamiliar with the use of ultrafiltration therapy, different ultrafiltration rates should have been utilized and adjusted according to patient characteristics, and that the diuretic regimen employed was not representative of standard-of-care. 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.[43] 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.[44] 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. 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. Despite being underpowered, the results of AVOID-HF indicated distinct trends toward reduced composite heart-failure events in the ultrafiltration group over 90 days. In addition, pre-specified secondary endpoints demonstrated significant reductions in heart failure and cardiovascular events re-hospitalization 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.

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

In October 2020, 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 Failur*e,"[45] 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.

In November 2020, we launched the ULTRA-PEDs pediatrics registry, a multi-center, single-arm study currently being conducted at six clinical sites.

In May 2021, a third-party systemic evaluation of eight randomized controlled trials, *"Ultrafiltration is better than diuretic therapy for volume-overloaded acute heart failure patients: a meta-analysis,"*[46] studied the effectiveness of ultrafiltration therapy compared to diuretics in 801 patients hospitalized with acute decompensated heart failure. The meta-analysis demonstrated ultrafiltration increases fluid removal and weight loss and reduces rehospitalization and the risk of worsening heart failure in congestive patients, suggesting ultrafiltration is a safe and effective treatment option for volume-overloaded heart failure patients.

In December 2021, we launched the REVERSE-HF prospective, multicenter, randomized controlled trial to evaluate ultrafiltration compared to IV diuretics in patients with heart failure. This RCT will be conducted at clinical sites nationwide with enrollment beginning in 2022. We expect to conduct additional clinical studies to provide further evidence of the safety and effectiveness of the Aquadex System.

Research and Development

Research and development costs include activities related to research, 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 clinical research.

In 2020, we initiated a product development project designed to improve peripheral venous access for the Aquadex FlexFlow® catheter and minimize filter clotting during the use of Aquadex System, and in 2021 initiated a product development project designed to enhance the functionality of the hematocrit sensor that is part of the Aquadex console. In 2021, we also initiated a product development project to develop a pediatric continuous renal replacement therapy device. We are also evaluating diagnostic tools for physicians to use during an Aquadex therapy to more precisely determine the amount of excess fluid to be removed, the rate of ultrafiltration, and when to stop therapy as dry weight is approached.

Manufacturers and Suppliers

We manufacture the Aquadex System at our 23,000 square foot facility in Eden Prairie, Minnesota. We have manufactured the Aquadex SmartFlow® console and blood circuits since its development in 2019. We purchase parts and components for the Aquadex System from third-party manufactures 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 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." Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven "required maintenance patents," and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. We estimate that the patents licensed from Baxter will expire between approximately 2021 and 2026.

[45]Watson RA, et al. J of Cardiac Fail. 2020 Oct; 26(10):S56.
[46]Wobbe, B., et al. Heart Failure Reviews. 2021 May; 26(3)): 577-585.

We have ten 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 2 granted US patents for the AcQtrac Cardiovascular Monitoring System. In addition, as of February 25, 2021 we owned 38 issued patents in the United States and in foreign jurisdictions related to our prior 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 between approximately 2020 and 2025. Given the strategic refocus away from 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.

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

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

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

Competition

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 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 also 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 continuous renal replacement therapy ("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.

Third-Party Reimbursement

In the United States, our products are purchased primarily by customers, such as hospitals or other health care providers. Customers bill various third-party payers for covered services 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 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 20 kilograms. The new CPT code provides additional reimbursement for therapeutic ultrafiltration administered in the outpatient setting.

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. 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 health care by challenging the prices charged, or deny coverage, for health care 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 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 wish 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 can exceed 90 days and may extend to a year or more.

After a device has received 510(k) clearance for a specific intended 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 intended use, will require a new 510(k) clearance The determination as to whether new 510K 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.

The Aquadex FlexFlow® system was granted FDA 510(k) clearance for commercial use on June 3, 2002. on February 4, 2020, we received 510(k) clearance of the Aquadex SmartFlow® system for use in adult and pediatric patients weighing 20 Kilograms or more whose fluid overload is unresponsive to medical management.

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

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

The results of clinical trial 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 trials may be delayed or halted or be inadequate to support clearance of a 510(K) application for numerous reasons.

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

- establishment registration and device listing upon the commencement of manufacturing;
- the Quality System Regulation (QSR), which requires manufacturers, including third-party manufacturers, to follow the FDA design control regulations;
- labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections; and
- product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDC Act caused by the device that may present a risk to health.

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

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

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

We and our contract manufacturers are also required to manufacture our products in compliance with Current Good Manufacturing Practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers is 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 MDD 90/385/EEC). The new MDR went into effect on May 26, 2021, and new CE Mark product must comply with new MDR after this date. As of May 26,2021, companies that have devices on the market with CE Mark under MDD 93/42/EEC or MDD 90/385/EEC must meet the transitional provisions of the new MDR. Devices lawfully placed on the market under MDD 93/42/EEC or MDD 90/385/EEC before May 26, 2021, may continue to be made available on the market until May 27, 2024, provided the CE Mark was issued prior to this date, the manufacturer continues to comply with either one of the directives, and that no significant changes are made in the design and intended purpose of the applicable medical device. By May 27, 2025, all medical devices entering the EU will need to have a new CE Mark under the MDR, even if they have been on the market previously under the MDD/AIMDD. Manufacturers are required to update their technical documentation and processes to meet the new requirements. Nuwellis™ received the CE Mark for Aquadex SmartFlow® on January 13, 2020. Nuwellis received the renewal certificate to include the 24-Hour blood circuit September 3rd, 2021. Our CE certificate for Aquadex SmartFlow® is under MDD/93/42 EEC and is valid through May 26,2024 which allow us to sell Aquadex SmartFlow® System into EU and satisfy future distribution demand.

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

Employees

As of February 25, 2022, we had 70 full-time employees. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Company History

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

Corporate Information

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

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

We are, and will remain, a “smaller reporting company” as long as our public float remains less than $250 million as of the last business day of our most recently-completed second fiscal quarter. A smaller reporting company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to U.S. public companies. As long as our public float remains below $75 million as of the last business day of our most recently completed second fiscal quarter, we are exempt from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404(b) of the Sarbanes-Oxley Act of 2002 (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 $19.6 million and $15.8 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, our accumulated deficit was $252.9 million.

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

We believe that we will need to raise additional capital to fund our operations through the second quarter of fiscal 2023. If additional capital is not available, we will have to delay, reduce or cease operations.

We believe that we will need to raise additional capital to fund our operations through the second quarter of 2023, however there can be no assurance of this. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, the risk that we may not be able to continue as a going concern may make it more difficult to obtain necessary additional funding on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, require us to use our cash to make payments under such indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions. If we are unable to secure additional funding, our development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations.

Our near-term prospects are highly dependent on revenues from a single product, the Aquadex System. We face significant challenges in expanding market acceptance of the Aquadex System, which could adversely affect our potential sales.

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

We depend on a limited number of customers, the loss of which, or failure of which to order our products in a particular period, could cause our revenues to decline.

Our ten largest customers represented 51.4% and 47.5% of our revenues in the years ended December 31, 2021 and 2020, respectively, with our largest customer representing 12.3% and 10.5%, respectively, of our revenues during such periods. Customer ordering patterns may vary significantly from quarter to quarter, or customers may discontinue providing therapies using our products. If one of our largest customers reduced its purchases in a fiscal period, our revenues for that period may be materially adversely affected. Further, if one of our largest customers discontinued the use of our products, our revenues may be materially adversely affected.

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

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

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

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

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

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

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

Several hospitals in the U.S. have included the Aquadex System into their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff are limited. However, we have also seen 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 has created significant uncertainty about our ability to access the capital markets in future periods. As of the filing date of this Annual Report on Form 10-K, the extent to which the COVID-19 pandemic may continue to impact our financial condition or results of operations or guidance is uncertain and cannot be reasonably estimated but could be material and last for an extended period of time. The effect of the COVID-19 pandemic may not be fully reflected in our results of operations and overall financial performance until future periods.

In addition, new variants of COVID-19have begun to spread globally and, in the United States, COVID-19 cases have increased significantly. The COVID-19 variants are limiting access and procedural volumes in some locations, which could adversely impact the Company's sequential and year-over-year growth.

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

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

As a result of the rise in COVID-19 cases due to the Omicron variant, hospitals are prioritizing and allocating beds and other resources for COVID-19 patients. In this regard, emergencies for patients with heart failure, unrelated to COVID-19, have decreased and there is less emergency usage of the Aquadex System. The impact of the Omicron variant has resulted in a decrease of our anticipated revenues for the fourth fiscal quarter of 2021.

If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute the Aquadex System effectively and our sales will suffer.

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

We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.

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

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

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

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

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

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

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

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

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

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

We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations.

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

The EU Medical Device Regulation 2017/745 (MDR) was adopted in April 2017. The MDR replaces the existing Medical Device Directives (MDD 93/42/EEC and MDD 90/385/EEC). The new MDR went into effect on May 26, 2021, and new CE Mark product must comply with new MDR after this date. As of May 26,2021, companies that have devices on the market with CE Mark under MDD 93/42/EEC or MDD 90/385/EEC must meet the transitional provisions of the new MDR. Devices lawfully placed on the market under MDD 93/42/EEC or MDD 90/385/EEC before May 26, 2021, may continue to be made available on the market until May 27, 2024, provided the CE Mark was issued prior to this date, the manufacturer continues to comply with either one of the directives, and that no significant changes are made in the design and intended purpose of the applicable medical device.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our Aquadex System and related components. On August 5, 2016, upon closing of our acquisition of the Aquadex Business, we entered into a patent license agreement with Baxter pursuant to which we obtained, for no additional consideration, a world-wide license to 49 exclusively licensed and 9 non-exclusively licensed patents used in connection with the Aquadex System to make, have made, use, sell, offer for sale and import, the Aquadex System in the “field of use” as defined in the license. The license is exclusive, with respect to some patents, and non-exclusive, with respect to other patents. Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven “required maintenance patents,” and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, or have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. We estimate that the patents licensed from Baxter will expire between approximately 2021 and 2026.

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

In addition, as of February 25, 2022, we owned 38 issued patents and one pending patent applications in the United States and in foreign jurisdictions related to our C-Pulse System and had one pending application for neuromodulation. We estimate that most of our currently issued U.S. patents will expire between approximately 2021 and 2027. Given the strategic refocus away from the C-Pulse System and towards the Aquadex System, we have chosen to limit the maintenance of issued C-Pulse System related patents to those innovations that are of the highest value. Further, we have elected to emphasize a few of the most critical jurisdictions rather than maintain the earlier approach that involved multiple countries.

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

Intellectual property litigation could be costly and disruptive to us.

In recent years, there has been significant litigation involving intellectual property rights in the medical device industry. From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in our business. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following:

- halt use of our Aquadex System;
- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or
- redesign our system.

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

If we were unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and system could be adversely affected.

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

Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.

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

In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed, and may in the future file, patent applications covering our system or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference or derivation proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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

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

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

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

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

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

Risks Related to Our Common Stock

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

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

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

On October 16, 2020, we effected a 1-for-30 reverse stock split of our outstanding common stock. In recent weeks, the closing price of our common stock been near the $1.00 minimum bid price for continued listing on the NASDAQ Capital Market. If we seek to implement a reverse stock split in the future to remain listed on the NASDAQ Capital Market, the announcement or implementation of a reverse stock split could significantly negatively affect the price of our common stock. Additionally, in 2020, the SEC approved a NASDAQ rule change to expedite delisting of securities of companies that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two-year period. Under the new rules, if a company falls out of compliance with the $1.00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any compliance periods and NASDAQ will instead require the issuance of a Staff delisting determination, which is appealable to a hearings panel. Our ability to remain listed on the NASDAQ Capital Market may be negatively impacted by this new NASDAQ rule.

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

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

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

As of February 25, 2022, we have warrants to purchase 1,631,798 shares of common stock outstanding, with exercise prices ranging from $2.50 to $41,916 with a weighted-average exercise price of $30.88.

As of February 25, 2022, there were 127 shares of Series F Preferred Stock outstanding, convertible into 50,800 shares of common stock. The certificate of designation for our Series F Preferred Stock contains an anti-dilution provision, which provision requires the lowering of the applicable conversion price, as then in effect, to the purchase price per share of common stock or common stock equivalents issued in the future. If the effective price per share on a common-stock equivalent basis in a future equity offering is lower than the then-current conversion price of the Series F Convertible Preferred Stock, then such conversion price shall be reduced to such lower price and additional shares of common stock will be issuable upon the conversion of the of the Series F Convertible Preferred Stock. To the extent the outstanding shares of Series F Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will experience further dilution.

If any security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock could depress the trading market for our common stock over an extended period of time.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2021, we have outstanding warrants to purchase an aggregate of approximately 1,631,798 shares of our common stock, and options to purchase an aggregate of approximately 754,525 shares of our common stock, which, if exercised, may further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market.

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

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

Our board of directors has previously approved, pursuant to this authority, the issuance of preferred stock, and we have 127 shares of Series F Preferred Stock outstanding as of February 25, 2022. Upon liquidation, dissolution or winding-up of the Company, holders of our Series F Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of such preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, pari passu with all the holders of common stock.

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

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 October 12, 2020, we effected a 1-for-30 reverse split of our outstanding common stock. This reverse stock split did not change the par value of our common stock or the number of common or preferred shares authorized by our Certificate of Incorporation. Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of February 25, 2022 our certificate of incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock, 127 of which are designated Series F Preferred Stock, and we have 10,537,606 shares of common stock outstanding, 2,437,123 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, and 361,666 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, 2021, we had U.S. net operating loss ("NOL") carryforwards of approximately $186.4 million for U.S. federal income tax purposes. Approximately $120.1 million of NOL carryforwards will expire from 2024 through 2037. Pursuant to the Tax Cuts and Jobs Act of 2017, the NOL carryforwards generated in 2018 through 2020 totaling approximately $66.3 million does not expire. The expiration of state NOL carryforwards will vary by jurisdiction. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code. As of December 31, 2021, the Company no longer had tax loss carryforwards in the Commonwealth of Australia due to the dissolution of the subsidiary in November 2020.

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We lease a 23,000 square foot facility located in Eden Prairie, Minnesota for office and manufacturing space under a non-cancelable operating lease that expires in March 2027. In November 2021, the Company entered into a fourth amendment to the lease, extending the term of the lease from March 31, 2022 to March 31, 2027. This facility serves as our corporate headquarters and houses substantially all our functional areas. Monthly rent and common area maintenance charges, including an estimate for property taxes for our headquarters, total approximately $29,000. 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.

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 material pending legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

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

Stockholders of Record. As of February 25, 2022, we had 10,537,606 shares of common stock issued and outstanding, and there were 3 holders of record of our common stock. A substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

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

ITEM 6. [Reserved].

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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

Overview

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

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

Impact of COVID-19 Pandemic

During the years ended December 31, 2021 and 2020, we were subject to challenging social and economic conditions created as a result of the outbreak of the novel strain of coronavirus, SARS-CoV-2. The resulting impact of the COVID-19 pandemic created disruptions in our operations resulting from rapid and evolving changes implemented to keep our customers, their patients, and our employees safe. These changes included restrictions on hospital access imposed on our field employees by customers dealing in the front lines of COVID-19 and managing the spread of the virus, changes to employees work practices by requiring employees to work remotely and increased protocols to ensure the safety of those employees that remained on site. The ongoing impact of the COVID-19 outbreak on our operational and financial performance will depend on certain future developments, including the duration and spread of the outbreak, the ongoing impact on our customers and hospital access restrictions imposed on our field employees, and effect on our vendors, all of which remain uncertain and cannot be predicted.

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

Several hospitals in the U.S. initially included the Aquadex System into their treatment protocol for fluid management of COVID-19, especially when dialysis equipment and staff were limited, but treatment regimens subsequently evolved so that the need to restore fluid balance became less prevalent. We estimate that approximately 1% and 14% of our U.S. revenue for the year ended December 31, 2021 and 2020, respectively, were driven by hospitals treating patients with COVID-19. However, we have also seen 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 has created significant uncertainty about our ability to access the capital markets in future periods. As of the filing date of this Form 10-K, the extent to which COVID-19 may continue to impact our financial condition or results of operations or guidance is uncertain and cannot be reasonably estimated but could be material and last for an extended period of time. The effect of the COVID-19 pandemic may not be fully reflected in our results of operations and overall financial performance until future periods. See Part 1, Item 1-A “Risk Factors” in this Annual Report on Form 10-K.

Recent Developments

Public Offerings

On September 17, 2021, the Company closed on an underwritten public offering of 4,005,588 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.

On March 19, 2021, we closed on an underwritten public offering of 3,795,816 shares of common stock, which includes 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.

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, 2021 as we have not experienced any 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 subassemblies and are recorded at the lower of cost or net realizable value using the first-in, first-out method.

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

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

Loss per share
Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders for the year ended December 31, 2021, includes a deemed dividend of $75,000 that resulted from the change in the exercise price of warrants as a result of the March 2021 and September 2021 offerings The net loss allocable to common stockholders for the twelve months ended December 31, 2020, reflects a $1.8 million increase for the net deemed dividend to preferred stockholders provided in connection with the close of the public offering of Series H Convertible Preferred Stock on January 28, 2020. This net deemed dividend includes $0.2 million that resulted from the subsequent reduction in the exercise of price of the warrants as a result of the March 2020 offering. (See Note 4 – Stockholder's 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 bypassed and the Company proceeded to fair value the asset group. The Company has determined the fair value of the asset group using expected cash flows associated with its loaner units by considering sales prices for similar assets and by estimating future discounted cash flows expected from the units. For recently acquired assets within the asset group, primarily equipment, the Company determined the fair value based on the replacement cost. Because the Company consists of one asset group, consideration is also given to the relationship between the Company's market capitalization and its carrying value to further support the Company's determination of fair value. There have been no impairment losses recognized for the years ended December 31, 2021 or 2020.

Going Concern

Our financial statements have been prepared and presented on a basis assuming we continue as a going concern. During the years ended December 31, 2021 and 2020, 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, 2021, we had an accumulated deficit of $252.9 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.

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, manufacturing components, 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 2020 and through December 31, 2021, we closed on underwritten public and other equity offerings for aggregate net proceeds of approximately $52.2 million after deducting the underwriting discounts and commissions or placement agents' fees and offering expenses, as applicable, and other costs associated with the offerings. In addition, during 2021 and 2020, we received approximately $1,300 and $4.1 million, respectively, in proceeds from the exercise of investor warrants. 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 proceeds from future warrant exercises, issuances of equity securities, or other financing transactions.

We believe that our existing capital resources will be sufficient to support our operating plan through June 30, 2023, however, there can be no assurance of this. We may seek to raise additional capital to support our growth or other strategic initiatives through debt, equity or a combination thereof.

Internal Controls and Procedures

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

RECENT ACCOUNTING PRONOUNCEMENTS

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

Information regarding new accounting pronouncements, when applicable, is included in Note 1 to the condensed 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 device company focused on commercializing the Aquadex System for ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy. Activities since inception have consisted principally of raising capital, performing research and development, and conducting 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 capabilities and transferring manufacturing capabilities of the Aquadex System from Baxter to our facilities in Eden Prairie, Minnesota. As of December 31, 2021, we had an accumulated deficit of $252.9 million and we expect to incur losses for the foreseeable future. To date, we have been funded by public and private equity financings, and debt. Although we believe that we will be able to successfully fund our operations in the future, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Net Sales
(dollars in thousands)

Year Ended December 31, 2021	Year Ended December 31, 2020	Increase (Decrease)	% Change
$ 7,921	$ 7,441	$ 480	6.5%

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, 2021 increased from console sales to both new and existing customers, along with higher circuit sales. However, sales during 2021 were negatively affected by the COVID-19 pandemic's impact on hospital access and procedural volumes, along with a change in treatment protocols that had benefited sales in 2020.

Costs and Expenses
Our costs and expenses were as follows:

(dollars in thousands)	Year Ended December 31, 2021	Year Ended December 31, 2020	Increase (Decrease)	% Change
Cost of goods sold	$ 3,430	$ 3,384	$ 46	1.4%
Selling, general and administrative	$ 19,039	$ 17,417	$ 1,622	9.3%
Research and development	$ 4,978	$ 3,668	$ 1,310	35.7%

Cost of Goods Sold
The increase in gross margin percent for the year ended December 31, 2021 compared to the year ended December 31, 2020 was due primarily to increased volumes and favorable mix.

Selling, General and Administrative
The increase in selling, general and administrative expense reflects our continued investment in sales and marketing activities, along with administrative costs.

Research and Development
The increase in R&D expenses over the prior year was primarily driven by investments in new products, along with increased clinical, regulatory and reimbursement activity. R&D expense included $428,160 for a non-refundable technology license fee, as discussed in Note 10 – Commitments and Contingencies.

Gain on Dissolution of Foreign Subsidiary
In November 2020, we dissolved our Australian subsidiary as no further business purpose existed and recognized a gain of $1.2 million related to cumulative foreign currency translation adjustments, previously recorded as part of other comprehensive income on our consolidated balance sheet.

Income Tax Expense

(dollars in thousands)	Year Ended December 31, 2021	Year Ended December 31, 2020	Increase (Decrease)	% Change
Income tax expense	$ 9	$ 9	$ —	0.0%

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

Liquidity and Capital Resources

Sources of Liquidity

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

On January 28, 2020, we closed on an underwritten public offering of 201,546 shares of common stock, 383,909 shares of Series H Preferred Stock and warrants to purchase 585,460 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 138,715 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 138,715 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 171,008 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 85,506 shares of the Company's common stock. The warrants are 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 119,930 shares of common stock for gross proceeds of approximately $1.7 million, prior to deduction of commissions and offering 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 59,966 shares of the Company's common stock. The warrants are 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 1,064,678 shares of common stock and warrants to purchase 1,064,678 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 3,795,816 shares of common stock, which includes 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 4,005,588 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.

As of December 31, 2021 and 2020, cash and cash equivalents were $24.2 million and $14.4 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 establishing a sales force, selling our products to hospitals and other healthcare facilities, and controlling costs. While we expect to continue to receive proceeds from the exercise of warrants, we will likely need to seek additional financing in the future, which, to date, has been through offerings of our equity. The disruption created by COVID-19 in our operations, our sales outlook, and the capital markets where we would seek such financing, have created uncertainty about our ability to access the capital markets in future periods.

Cash Flows from Operating Activities

Net cash used in operating activities was $17.9 million and $16.6 million in 2021 and 2020, 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, the gain on the dissolution of a foreign subsidiary, and the effects of changes in operating assets and liabilities, including working capital.

Cash Flows from Investing Activities

Net cash used in investing activities was $0.2 million and $0.3 million in 2021 and 2020, respectively. The cash used in investing activities was for the purchase of manufacturing, laboratory and office equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $27.9 million and $30.0 million in 2021 and 2020, respectively.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2021, which represent material expected or contractually committed future obligations:

(Dollars in thousands)	Payments Due by Period				
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Operating Lease	$ 213	$ 506	$ 605	$ -	$ 1,324
Financing Leases	29	32	-	-	61
Total	$ 242	$ 538	$ 605	$ -	$ 1,385

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 $29,000. 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, 2021, 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.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nuwellis, Inc. and subsidiaries (the "Company") as of December 31, 2021 and 2020, 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, 2021 and 2020, and the results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments.

The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Critical Audit Matter Descriptions

Evaluation of long-lived assets for impairment

As described in Note 1 to the consolidated financial statements, the Company evaluates its long-lived assets, primarily property and equipment, for impairment whenever events and circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

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

As the Company expects to continue incurring losses in the foreseeable future, the undiscounted cash flow step was bypassed, and the Company proceeded to fair value the asset group. The Company has determined the fair value of the asset group using a composite approach. It is based on the expected cash flows associated with each of the components of the asset group. For the loaner units, the Company considered the sales prices for similar assets as well as by estimating future discounted cash flows expected from the units. For recently acquired assets within the asset group, primarily equipment, the Company determined the fair value based on the replacement cost. For the right of use asset, the Company used the ending market value from its property tax statement times the percentage of the building that it occupies. The Company used this method to approximate the fair value of the right of use asset.

Considerable management judgment is necessary to estimate the fair value of the asset group; therefore, we considered the evaluation of long-lived assets for impairment as a critical audit matter.

How We Addressed the Matter in Our Audit

As part of our risk assessment procedures, we evaluated the design and implementation of the Company's controls over its process to evaluate the presence of indicators of potential impairment at the end of each reporting period. We also evaluated the design and implementation of the Company's controls over its use of estimates and assumptions in the calculation of the asset group's fair value. We assessed the Company's conclusions regarding the interrelation of its cash flows between its various long-lived assets to determine if we agreed with the determination that there is one asset group.

As the Company bypassed the undiscounted cash flows test, we obtained the Company's analysis for estimating the fair value and tested the completeness and accuracy of the relevant inputs and assumptions. We performed testing on the estimated discounted cash flows expected from certain assets within the asset group by considering historical cash flows from these assets and analyzing the appropriateness of assumptions regarding the future discounted cash flows. We tested a sample of sales prices of similar assets to those assets within the asset group and tested a sample of the costs paid for acquisition of long-lived assets in the current year to corroborate the replacement cost of these assets. We also evaluated the discount rate used in the analysis. We performed inquiries to corroborate the expected cash flows with individuals within the Company's sales and marketing team. Finally, we obtained the property tax statement, recalculated the fair value determined by the Company, and performed sensitivity analysis. We also compared fair value per square foot to similar properties for sale in the area to gain additional comfort over the fair value.

Evaluation of Company's ability to Continue as a Going Concern

As described in Note 1 to the consolidated financial statements, the Company evaluates its ability to continue as a going concern for at least 12 months from our report date. The Company has historically incurred losses from operations, net cash outflows from operating activities, and has an accumulated deficit. The Company expects to incur additional losses in the near-term as it grows its business and will require additional financings to fund itself. 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. As a result, the Company evaluated whether there is substantial doubt around its ability to continue as a going concern as of December 31, 2021.

The Company prepared an evaluation of its ability to continue as a going concern. This evaluation included cash flow projections, as well as a going concern memo detailing management's plans for the look-forward period. Management's future plans and projections of future cash flows contain uncertainties and are based on significant management judgment.

We identified the going concern assessment as a critical audit matter. Auditing management's judgments regarding the execution of its plans and the associated forecasted cash flows involves a high degree of subjectivity.

How We Addressed the Matter in Our Audit

As part of our risk assessment procedures, we evaluated the design and implementation of the Company's controls over its process to evaluate the ability to continue as a going concern at the end of each reporting period. We also evaluated the design and implementation of the Company's controls over its use of estimates and assumptions in the Company's projections.

The Company determined there were conditions or events that raised substantial doubt regarding its ability to continue as a going concern (step 1) and therefore considered whether its plans alleviated substantial doubt (step 2). We obtained the Company's analysis for alleviating substantial doubt, which included a memo detailing its plans and projections through December 31, 2023. We tested the completeness and accuracy of the relevant inputs and assumptions and assessed the reasonableness and support management has around its plans. We performed sensitivity testing on the projections to determine whether or not if projections were missed would the Company still have sufficient cash on hand to fund its operations for at least twelve months from the report date. We performed inquiries to corroborate the projections with individuals within the Company's accounting and finance team and discussed with the Board of Directors.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2017.

Minneapolis, Minnesota
March 03, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 24,205	$ 14,437
Accounts receivable	750	905
Inventories	2,843	2,957
Other current assets	328	237
Total current assets	28,126	18,536
Property, plant and equipment, net	1,188	1,200
Operating lease right-of-use asset	1,082	255
Other assets	21	21
TOTAL ASSETS	$ 30,417	$ 20,012
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,414	$ 1,097
Accrued compensation	1,664	2,192
Current portion of operating lease liability	167	206
Current portion of finance lease liability	26	24
Other current liabilities	36	66
Total current liabilities	3,307	3,585
Operating lease liability	956	55
Finance lease liability	28	54
Other long-term liability	179	—
Total liabilities	4,470	3,694
Commitments and contingencies		
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2021 and December 31, 2020, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of December 31, 2021 and December 31, 2020, par value $0.0001 per share; authorized 127 shares, issued and outstanding 127 shares	—	—
Preferred stock as of December 31, 2021 and December 31, 2020, par value $0.0001 per share; authorized 39,969,873 shares, none outstanding	—	—
Common stock as of December 31, 2021 and December 31, 2020, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 10,537,606 and 2,736,060, respectively	1	—
Additional paid-in capital	278,873	249,663
Accumulated other comprehensive income:		
Foreign currency translation adjustment	(11)	(7)
Accumulated deficit	(252,916)	(233,338)
Total stockholders' equity	25,947	16,318
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 30,417	$ 20,012

See notes to the consolidated financial statements

NUWELLIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)

	Year Ended December 31, 2021	2020
Net sales	$ 7,921	$ 7,441
Cost of goods sold	3,430	3,384
Gross profit	4,491	4,057
Operating expenses:		
Selling, general and administrative	19,039	17,417
Research and development	4,978	3,668
Total operating expenses	24,017	21,085
Loss from operations	(19,526)	(17,028)
Realized foreign currency translation gain from dissolution of subsidiary	—	1,202
Other income (expense), net	(43)	(1)
Loss before income taxes	(19,569)	(15,827)
Income tax expense	(9)	(9)
Net loss	$ (19,578)	$ (15,836)
Basic and diluted loss per share	$ (2.87)	$ (10.67)
Weighted average shares outstanding – basic and diluted	6,852	1,649
Other comprehensive loss:		
Realized foreign currency translation gain from dissolution of subsidiary	$ —	$ (1,202)
Unrealized foreign currency translation adjustment	(4)	(19)
Total comprehensive loss	$ (19,582)	$ (17,057)

See notes to the consolidated financial statements

NUWELLIS, INC. AND SUBSIDIARIES

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, 2019	**155,802**	**$ —**	**$ 218,278**	**$ 1,214**	**$ (217,502)**	**$ 1,990**
Net loss	—	—	—	—	(15,836)	(15,836)
Realized foreign currency translation gain from dissolution of subsidiary	—	—	—	(1,202)	—	(1,202)
Unrealized foreign currency translation adjustment	—	—	—	(19)	—	(19)
Stock-based compensation, net	—	—	1,349	—	—	1,349
Issuance of common stock, net	1,695,877	—	25,921	—	—	25,921
Exercise of warrants	455,139	—	4,115	—	—	4,115
Conversion of preferred stock into common stock	429,242	—	—	—	—	—
Balance December 31, 2020	**2,736,060**	**$ —**	**$ 249,663**	**$ (7)**	**$ (233,338)**	**$ 16,318**
Net loss	—	—	—	—	(19,578)	(19,578)
Unrealized foreign currency translation adjustment	—	—	—	(4)	—	(4)
Stock-based compensation, net	—	—	1,314	—	—	1,314
Issuance of common stock, net	7,801,404	1	27,895	—	—	27,896
Exercise of warrants	142	—	1	—	—	1
Balance December 31, 2021	**10,537,606**	**$ 1**	**$ 278,873**	**$ (11)**	**$ (252,916)**	**$ 25,947**

See notes to the consolidated financial statements

NUWELLIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

	For the years ended December 31,	
	2021	**2020**
Operating Activities		
Net loss	$ (19,578)	$ (15,836)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	488	376
Stock-based compensation expense, net	1,314	1,349
Loss on disposal of property and equipment	—	40
Realized foreign currency translation gain from dissolution of subsidiary	—	(1,202)
Changes in operating assets and liabilities:		
Accounts receivable	155	(106)
Inventory	(143)	(1,420)
Other current assets	(91)	(76)
Other assets and liabilities	186	112
Accounts payable and accrued expenses	(211)	191
Net cash used in operations	(17,880)	(16,572)
Investing activities:		
Purchase of property and equipment	(219)	(298)
Proceeds from sale of property and equipment	—	31
Net cash used in investing activities	(219)	(267)
Financing activities:		
Proceeds from public stock offerings, net	27,896	25,921
Proceeds from warrant exercises	1	4,115
Payments on finance lease liability	(26)	(20)
Net cash provided by financing activities	27,871	30,016
Effect of exchange rate changes on cash	(4)	(19)
Net increase in cash and cash equivalents	9,768	13,158
Cash and cash equivalents—beginning of year	14,437	1,279
Cash and cash equivalents—end of year	$ 24,205	$ 14,437
Supplemental schedule of non-cash activities		
Inventory transferred to property, plant and equipment	$ 257	$ 260
Equipment acquired through finance lease liability	$ —	$ 98
Operating right-of-use asset recorded as an operating lease liability	$ 901	$ —
Supplemental cash flow information		
Cash paid for income taxes	$ 11	$ 10

See notes to the consolidated financial statements

NUWELLIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

Note 1—Nature of Business and Significant Accounting Policies

Nature of Business

Nuwellis, Inc. (the "Company") is a medical device 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 20kg or more whose fluid overload is unresponsive to medical management, including diuretics. Nuwellis, Inc. is a Delaware corporation headquartered in Minneapolis with 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.

Liquidity

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, 2021 and 2020, 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, 2021, the Company had an accumulated deficit of $252.9 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.

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, 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 2020 and through December 31, 2021, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately $52.2 million after deducting the underwriting discounts and commissions and other costs associated with the offerings. In addition, during 2021 and 2020 we received approximately $1,300 and $4.1 million, respectively, in proceeds from the exercise of investor warrants. 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 June 30, 2023. However, the Company may seek to raise additional capital to support its growth or other strategic initiatives through debt, equity or a combination thereof. There can be no assurance we will be successful in raising additional capital.

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Nuwellis, Inc. and its wholly-owned subsidiaries, Nuwellis, LLC, Sunshine Heart Company Pty Ltd (through November 2020) and Sunshine Heart Ireland Limited. All intercompany accounts and transactions between consolidated entities have been eliminated. During the year ended December 31, 2020, the Company closed its Australian subsidiary and recognized a gain of $1.2 million on the dissolution of the entity, due to the recognition of previously unrealized foreign currency translation gains. This subsidiary represented an immaterial portion of our operations, and the dissolution did not represent a strategic shift and therefore, is not presented as a discontinued operation.

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 approximate fair value. The balances, at times, may exceed federally insured limits. The Company has not experienced any losses on its cash and cash equivalents.

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 of the aging of its accounts receivable, and therefore, no allowance for doubtful accounts was considered necessary as of December 31, 2021 or December 31, 2020. As of December 31, 2021, two customers represented 12% and 11% of the accounts receivable balance. As of December 31, 2020, no customer represented over 10% of the 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. Inventories consisted of the following as of December 31:

	2021	2020
Finished Goods	$ 1,409	$ 1,343
Work in Process	276	342
Raw Materials	1,158	1,272
Total	$ 2,843	$ 2,957

Other Current Assets

Other current assets represent prepayments and deposits made by the Company.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Depreciation is computed based upon the estimated useful life of the respective asset. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful life of the assets. Repairs and maintenance cost is expensed as incurred. The cost and accumulated depreciation of property, plant and equipment retired, or otherwise disposed of is removed from the related accounts, and any residual values are charged to expense. Depreciation expense has been calculated using the following estimated useful lives:

Production Equipment	3-7 years
Office Furniture and Fixtures	3-5 years
Computer Software and Equipment	3-4 years
Loaners and demo equipment	1-5 years
Leasehold improvements	3-5 years

Depreciation expense was $488,000 and $376,000 for the years ended December 31, 2021 and 2020, 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 expected cash flows associated with its loaner units by considering sales prices for similar assets and by estimating future discounted cash flows expected from the units. For recently acquired assets within the asset group, primarily equipment, the Company determined the fair value based on the replacement cost. For the operating lease right-of-use asset the Company compared its carrying value to an estimated fair market value calculated as its occupancy percentage based off of the most recent property tax statement. Because the Company consists of one asset group, consideration is also given to the relationship between the Company's market capitalization and its carrying value to further support the Company's determination of fair value. There have been no impairment losses recognized for the years ended December 31, 2021 or 2020.

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 years ended December 31, 2021, two customers represented 12.3% and 10.7% of net sales. For the years ended December 31, 2020, one customer represented 10.5% 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 recognized to 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 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.

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. 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 the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Loss per share

Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders for the year ended December 31, 2021, includes a deemed dividend of $75,000 that resulted from the change in the exercise price of warrants as a result of the March 2021 and September 2021 offerings. The net loss allocable to common stockholders for the year ended December 31, 2020, reflects a $1.8 million increase for the net deemed dividend to preferred stockholders provided in connection with the close of the public offering of Series H Convertible Preferred Stock on January 28, 2020. This net deemed dividend includes $0.2 million that resulted from the subsequent reduction in the exercise of price of the warrants as a result of the March 2020 offering (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,	
	2021	**2020**
Stock options	754,525	16,889
Warrants to purchase common stock	1,631,798	1,631,948
Series F convertible preferred stock	50,800	14,224
Total	2,437,123	1,663,061

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)	**2021**	**2020**
Net loss	$ (19,578)	$ (15,836)
Deemed dividend to preferred stockholders (see Note 4)	(75)	(1,757)
Net loss after deemed dividend	(19,653)	(17,593)
Weighted average shares outstanding	6,852	1,649
Basic and diluted loss per share	$ (2.87)	$ (10.67)

Research and Development

Research and development costs include activities related to research, development, design, and testing improvements of the Aquadex System and potential related products. Research and development costs also include expenses related to clinical research that the Company may sponsor or conduct to enhance understanding of the product and its use. Research and development expenses are expensed as incurred.

Recent Accounting Pronouncements

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

The Company evaluates events through the date the consolidated financial statements are filed for events requiring adjustment to or disclosure in the consolidated financial statements.

Note 2 – Revenue Recognition

Net Sales

The Company sells its products in the United States primarily through a direct sales force. Customers who purchase the Company's products include hospitals and clinics throughout the United States. In countries outside the United States, the Company sells its products through a limited number of specialty healthcare distributors in Austria, Brazil, Czech Republic, Germany, Greece, Hong Kong, India, Israel, Italy, Romania, Singapore, Slovakia, Spain, Switzerland, Thailand, United Arab Emirates, and the United Kingdom. These distributors resell the Company's products to hospitals and clinics in their respective geographies.

Revenue from product sales is recognized when the customer or distributor obtains control of the product, which occurs at a point in time, most frequently upon shipment of the product or receipt of the product, depending on shipment terms. The Company's standard shipping terms are FOB shipping point unless the customer requests that control and title to the inventory transfer upon delivery. Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when the Company satisfies its performance obligations under the contract. The majority of the Company's contracts have a single performance obligation and are short term in nature. The Company has entered into extended service plans with customers which are recognized over time. This revenue represents less than 1% of net sales for each of the years ended December 31, 2021 and 2020. The unfulfilled performance obligations related to these extended service plans is included in deferred revenue, which is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

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

Product Returns: The Company offers customers a limited right of return for its product in case of non-conformity or performance issues. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own historical sales and returns information. The Company has not received any returns to date and believes that future returns of its products will be minimal. Therefore, revenue recognized is not currently impacted by variable consideration related to product returns.

Note 3—Property, Plant and Equipment

Property, plant and equipment were as follows:

(in thousands)	**December 31, 2021**	**December 31, 2020**
Production Equipment	$ 1,321	$ 1,201
Loaners and Demo Equipment	1,364	1,073
Computer Software and Equipment	714	691
Office Furniture & Fixtures	364	364
Leasehold Improvements	245	242
Total	4,008	3,571
Accumulated Depreciation	(2,820)	(2,371)
	$ 1,188	$ 1,200

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 an initial conversion price of $1,890.00 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 $1,890.00 per share, and a Series 2 warrant, which expires on the seventh anniversary of its issuance, to purchase 16 shares of the Company's common stock at an exercise price of $1,890.00 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 initially convertible into 9,557 shares of common stock and warrants to purchase 19,122 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 $890.40 to $157.50, 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 $157.50 to $42.30, and on November 6, 2019, from $42.30 to $29.83, 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 $29.83 to $16.50, 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 $16.50 to $9.00, 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 $5.50 to $2.50, the per share price to the public in the September 2021 offering, described below.

As of December 31, 2021, and December 31, 2020, 127 shares of the Series F convertible preferred stock remained outstanding.

Series H Convertible Preferred Stock and January 2020 Offering: On January 28, 2020, the Company closed on an underwritten public offering of common stock, Series H convertible preferred stock and warrants to purchase shares of common stock for gross proceeds of $9.7 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants ("January 2020 Offering"). Net proceeds totaled approximately $8.6 million after deducting the underwriting discounts and commissions and other costs associated with the offering. The Series H convertible preferred stock included a beneficial conversion amount of $1.6 million, representing the intrinsic value of the shares at the time of issuance, and $0.2 million of down-round protection in connection with the re-pricing of the warrants following the March 2020 offering described below. This amount is reflected as an increase to the loss per share allocable to common stockholders in the year ended December 31, 2020.

The January 2020 Offering was comprised of 201,546 shares of common stock priced at $16.50 per share and 11,517,269 shares of Series H convertible preferred stock, convertible into common stock at $16.50 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 585,460 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 $16.50 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 $16.50 to $9.00, the per share price to the public in the March 2020 offering, described below.

As of December 31, 2020, all 11,517,269 shares of the Series H convertible preferred stock had been converted into common stock and none remained outstanding. As of December 31, 2020, warrants to purchase 455,162 shares of common stock had been exercised for total cash proceeds of $4.1 million.

March 2020 Offering: On March 23, 2020, the Company closed on a registered direct offering of 138,715 shares of its common stock at a price to the public of $9.00 per share, for gross proceeds of approximately $1.2 million, or $1.0 million net after deducting commissions and offering expenses payable by Nuwellis. In a concurrent private placement, the Company agreed to issue to the investors in the registered direct offering warrants to purchase up to 138,715 shares of the Company's common stock. The warrants to purchase up to 138,715 shares of common stock have an exercise price of $11.18 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 171,008 shares of its common stock at a price to the public of $13.02 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 85,506 shares of the Company's common stock. The warrants have an exercise price of $11.15 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 119,930 shares of its common stock at a price to the public of $14.18 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 59,966 shares of the Company's common stock. The warrants have an exercise price of $12.30 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 1,064,678 shares of common stock priced at $13.50 per share. Each share of common stock was accompanied by a warrant to purchase common stock. The warrants are exercisable into 1,064,678 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 3,795,816 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 $9.00 to $5.50, 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 $9.00 to $5.50, 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 4,005,588 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 $5.50 to $2.50, 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 $5.50 to $2.50, the per share price to the public in the September 2021 Offering.

Placement Agent Fees: In connection with the offerings described above, the Company paid the placement agents an aggregate cash placement fee equal to 8% of the aggregate gross proceeds raised in each of the offerings.

Market-Based Warrants: On May 30, 2019, the Company granted a market-based warrant to a consultant in exchange for investor relations services. The warrant represents the right to acquire up to 3,334 shares of the Company's common stock at an exercise price of $95.40 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. The warrant was valued at $57.90 per share using the Monte Carlo valuation methodology and was expensed over the term of the consulting engagement which was twelve months. Significant inputs used for the Monte Carlo valuation were the expected stock price volatility of 136.21%, and management's expectations regarding the timing of regulatory clearance for an expanded label in pediatrics. None of these warrants had vested as of December 31, 2021.

Reverse Stock Split: On October 6, 2020, the Company's stockholders approved a reverse split of its outstanding common stock at a ratio in the range of 1-for-5 to 1-for-30 and, on October 9, 2020, the board of directors approved a 1-for-30 reverse split of the Company's outstanding common stock that became effective after trading on October 16, 2020. This reverse stock split did not change the par value of the Company's common stock or the number of common or preferred shares authorized by the Company's Fourth Amended and Restated Certificate of Incorporation, as amended. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

Note 5— Stock-Based Compensation

Stock Options and Restricted Stock Awards

The Company has various share-based compensation plans, including the Third Amended and Restated 2017 Equity Incentive Plan, the 2013 Non-Employee Directors' Equity Incentive Plan and the 2021 Inducement Plan (collectively, the ***"Plans"***). The Plans are designed to assist in attracting, motivating and retaining employees and directors and to recognize the importance of employees to the long-term performance and success of the Company. The Company has also granted stock options to certain non-employees outside of the Plans.

The Company recognized stock-based compensation expense related to grants of stock options and common stock awards to employees, directors and consultants of $1.3 million, and $1.3 million during the years ended December 31, 2021 and 2020, respectively. The following table summarizes the stock-based compensation expense which was recognized in the consolidated statements of operations for the years ended December 31,

(Dollars in thousands)	**2021**	**2020**
Selling, general and administrative	$ 1,171	$ 1,252
Research and development	143	97
Total	$ 1,314	$ 1,349

The majority of the RSUs 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:

	2021		**2020**	
	Options Outstanding	**Weighted Average Exercise Price**	**Options Outstanding**	**Weighted Average Exercise Price**
Beginning Balance	16,889	$ 405.34	13,471	$ 515.33
Granted	912,999	4.46	5,542	10.03
Exercised	—	—	—	—
Forfeited/expired	(175,363)	27.76	(2,124)	71.51
Outstanding at December 31	754,525	$ 8.00	16,889	$ 405.34
Vested at December 31	43,691	$ 64.16	7,254	$ 697.37

For options outstanding and vested at December 31, 2021, the weighted average remaining contractual life was 9.38 years and 9.09 years, respectively. There were no option exercises in 2021 or 2020. The total fair value of options that vested in 2021 and 2020 was $0.7 million, and $1.7 million, respectively, at the fair value of the options as of the date of grant.

Valuation Assumptions: The fair value of each stock option is estimated at the grant date using the Black-Scholes option pricing model. The fair value of stock options under the Black-Scholes option pricing model requires management to make assumptions regarding projected employee stock option exercise behaviors, risk-free interest rates, volatility of the Company's stock price, and expected dividends.

The Company has not historically paid cash dividends to its stockholders, and currently does not anticipate paying any cash dividends in the foreseeable future. As a result, the Company has assumed a dividend yield of 0%. The risk-free interest rate is based upon the rates of U.S. Treasury bills with a term that approximates the expected life of the option. Since the Company has limited historical exercise data to reasonably estimate the expected life of its option awards, the expected life is calculated using a simplified method. Expected volatility is based on historical volatility of the Company's stock.

The following table provides the weighted average assumptions used in the Black-Scholes option pricing model for the years ended December 31:

	2021	2020
Expected dividend yield	0%	0%
Risk-free interest rate	1.19%	0.65%
Expected volatility	131.03%	127.87%
Expected life (in years)	6.21	5.91

The weighted-average fair value of stock options granted in 2021 and 2020 was $3.98 and $8.79, respectively. As of December 31, 2021, the total compensation cost related to all non-vested stock option awards not yet recognized was approximately $2.4 million and is expected to be recognized over the remaining weighted-average period of 3.19 years.

Warrants: Warrants to purchase 1,631,798 and 1,631,948 shares of common stock were outstanding on December 31, 2021 and 2020, respectively. As of December 31, 2021, warrants outstanding were exercisable at prices ranging from $2.50 to $41,916 per share, and are exercisable over a period ranging from 3 months to 3.85 years.

Note 6—Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents 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.

The fair value of the market-based warrants described in Note 4 was calculated using a Monte Carlo valuation model and was classified as Level 3 in the fair value hierarchy. These warrants were classified as permanent equity and as a result, were measured at the grant date and are not required to be remeasured to fair value at each reporting period end.

All cash equivalents are considered Level 1 measurements for all periods presented. The Company does not have any financial instruments classified as Level 2 or Level 3 and there were no movements between these categories as of December 31, 2021 and December 31, 2020. The Company believes that the carrying amounts of all remaining financial instruments approximate their fair value due to their relatively short maturities.

Note 7—Income Taxes

Domestic and foreign income (loss) before income taxes, consists of the following for the years ended December 31:

(in thousands)	2021	2020
Domestic	$ (19,606)	$ (15,865)
Foreign	37	38
Loss before income taxes	$ (19,569)	$ (15,827)

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

(in thousands)	2021	2020
Current:		
United States and state	$ —	$ —
Foreign, net	(9)	(9)
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax expense	$ (9)	$ (9)

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

(in thousands)	2021	2020
Statutory federal income tax benefit	$ 4,109	$ 3,324
State tax benefit, net of federal taxes	560	94
Foreign tax	(1)	(1)
Foreign deferred exchange rate adjustments	—	1,027
Dissolution of foreign subsidiary	—	(11,401)
Nondeductible/nontaxable items	(220)	34
Other	406	(255)
Valuation allowance (increase) decrease	(4,863)	7,169
Total income tax expense	$ (9)	$ (9)

Deferred taxes consist of the following as of December 31:

(in thousands)	2021	2020
Deferred tax assets:		
Noncurrent:		
Accrued leave	$ 59	$ 61
Stock based compensation	368	293
Net operating loss carryforward	42,363	37,665
Other	131	11
Intangibles	723	751
R&D credit carryforward	531	531
Total deferred tax assets	44,175	39,312
Less: valuation allowance	(44,175)	(39,312)
Total	$ —	$ —

As of December 31, 2021, the Company had federal net operating loss (“NOL”) carryforwards of approximately $186.4 million and state NOL carryforwards of $44.4 million. Approximately $120.1 million of federal NOL carryforwards will expire between 2025 and 2038. Pursuant to the Tax Cuts and Jobs Act of 2017, NOLs generated after 2017 of approximately $66.3 million do not expire. The expiration of state NOL carryforwards will vary by jurisdiction. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code. As of December 31, 2020, the Company no longer has tax loss carryforwards in the Commonwealth of Australia due to the dissolution of the subsidiary in November 2020.

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of the deferred tax assets. The Company has established a valuation allowance for U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying consolidated financial statements. For the years ended December 31, 2021, and 2020, the valuation allowance increased by $4.9 million and decreased by $7.2 million, respectively. The current year increase was primarily due to the Federal and state net operating losses generated.

During 2018, 2019, 2020 and 2021, the Company believes it experienced an ownership change as defined in Section 382 of the Internal Revenue Code which will limit the ability to utilize the Company’s net operating losses (NOLs). The Company may have experienced additional ownership changes in earlier years further limiting the NOL carry-forwards 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, 2021 or 2020.

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, 2021 and 2020, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The tax years ended December 31, 2018 through December 31, 2021 remain open to examination by the Internal Revenue Service and for the various states where the Company is subject to taxation. Additionally, the returns of the Company's Australian (through November 2020) and Irish subsidiaries are subject to examination by tax authorities of those jurisdictions for the tax years ended and subsequent to June 30, 2016 and December 31, 2016, respectively.

Note 8—Operating Leases

The Company leases a 23,000 square foot facility located in Eden Prairie, Minnesota for office and manufacturing space under a non-cancelable operating lease that expires in March 2027. In November 2021, the Company entered into a fourth amendment to the lease, extending the term of the lease from March 31, 2022 to March 31, 2027. This facility serves as our corporate headquarters and houses substantially all our functional areas. Monthly rent and common area maintenance charges, including estimated property tax for our headquarters total approximately $29,000. 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 is $10.50 per square foot, subject to annual increases of $0.32 to $0.34 per square foot.

The cost components of the Company's operating lease were as follows for the year ended December 31:

(in thousands)	**2021**	**2020**
Operating lease cost	$ 219	$ 213
Variable lease cost	123	114
Total	**$ 342**	**$ 327**

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)	**2021**
2022	$ 213
2023	249
2024	257
2025	264
2026	272
2027	69
Total lease payments	1,324
Less: Interest	(201)
Present value of lease liability	**$ 1,123**

As of December 31, 2021, and 2020, the remaining lease terms were 5.25 and 1.25 years, respectively, and discount rates were 7.5% for each year. For the years ended December 31, 2021, and 2020, the operating cash outflows from the Company's operating lease for office and manufacturing space were $219,000 and $213,000, 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)-profit sharing 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 employee's contributions at the discretion of the Company. Matching contributions totaled $293,000 and $234,000 for the years ended December 31, 2021 and 2020, respectively.

Non-refundable Technology License Fee

On June 24, 2021, the Company entered into a research and development collaboration agreement with Koronis Biomedical Corporation (KBT) to design and develop an integrated continuous renal replacement therapy device. This agreement became effective on August 5, 2021, when KBT received approval of a $1.7 million grant from the National Institutes of Health (NIH) to support this project. As part of this agreement, the Company will pay KBT a non-refundable technology license fee of $428,160, payable in twelve equal monthly installments commencing on June 1, 2022. The Company has recorded a liability for the non-refundable technology license fee with $249,760 included in Current Accounts Payable and $178,400 included in Other Long-term Liabilities. The full amount of $428,160 was expensed and included in the Research and Development Expense line for the year ended December 31, 2021.

Note 11—Related Party Transactions

There were no related party transactions requiring disclosure during the year ended December 31, 2021 and 2020.

Note 12—Segment and Geographic Information

The Company has one reportable segment, fluid management.

At December 31, 2021 and 2020, long-lived assets were located primarily in the United States.

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, 2021, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2021.

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, 2021, the end of our fiscal year. Management based its assessment on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2021.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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

Item 11. Executive Compensation.

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

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

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

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

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

Item 14. Principal Accounting Fees and Services.

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

PART IV

Item 15. Exhibits, and Financial Statement Schedules.

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

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

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

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
2.1	Asset Purchase Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	2.1	
3.1	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1	
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1	
3.3	Certificate of Amendment to 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	Second Amended and Restated Bylaws	8-K	001-35312	April 27, 2021	3.2	
3.9	Form of Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	001-35312	June 14, 2013	3.1	
3.10	Form of Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	S-1/A	333-221010	November 17, 2017	3.7	
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock	8-K	001-35312	March 13, 2019	3.1	
3.12	Certificate of Designation of Preferences, Rights and Limitations of Series H Convertible Preferred Stock	8-K	001-35312	January 29, 2020	3.1	
4.1	Warrant to Purchase Stock, dated February 18, 2015, issued to Silicon Valley Bank	8-K	001-35312	February 19, 2015	4.1	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
4.2	Warrant to Purchase Stock, dated February 18, 2015, issued to Life Science Loans, LLC	8-K	001-35312	February 19, 2015	4.2	
4.3	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated July 20, 2016, among the Company and the purchasers signatory thereto	8-K	001-35312	July 22, 2016	4.2	
4.4	Form of common stock Purchase Warrant issued to Northland Securities, Inc.	8-K	001-35312	July 22, 2016	4.3	
4.5	Registration Rights Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	4.1	
4.6	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated October 30, 2016, among the Company and the purchasers signatory thereto	8-K	001-35312	October 31, 2016	4.1	
4.7	Form of common stock Purchase Warrant issued pursuant to the Letter Agreement between the Company and the purchasers signatory thereto, dated February 15, 2017	8-K	001-35312	February 16, 2017	4.1	
4.8	Form of common stock Purchase Warrant issued pursuant to the Underwriting Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated April 19, 2017	S-1/A	333-216841	April 4, 2017	4.8	
4.9	Form of Warrant to purchase shares of common stock	S-1/A	333-221010	November 17, 2017	4.9	
4.10	Form of Series 1 and Series 2 Warrant to Purchase Shares of Common Stock	S-1/A	333-209102	February 25, 2019	4.10	
4.11	Common Stock Purchase Warrant, dated May 30, 2019, between the Company and Redington, Inc.	10-Q	001-35312	August 8, 2019	4.1	
4.12	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	
4.13	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.1	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
4.14	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	
4.15	Form of Common Stock Purchase Warrant	S-1/A	333-235385	January 23, 2020	4.15	
4.16	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	
4.17	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	
4.18	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	
4.19	Form of Warrant to Purchase Shares of Common Stock	S-1/A	333-24145	August 17, 2020	4.19	
4.20	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	Loan and Security Agreement between Sunshine Heart, Inc. and Silicon Valley Bank dated August 5, 2016	8-K	001-35312	August 8, 2016	10.2	
10.3	Amended and Restated 2002 Stock Plan†	10	001-35312	December 16, 2011	10.2	
10.4	Form of Notice of Stock Option Grant and Option Agreement for Amended and Restated 2002 Stock Plan†	10	001-35312	September 30, 2011	10.3	
10.5	Second Amended and Restated 2011 Equity Incentive Plan, as amended†	14A	001-35312	July 27, 2012	App. A	
10.6	Form of Stock Option Grant Notice and Option Agreement for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.5	
10.7	Form of Stock Option Grant Notice and Option Agreement (Senior Management) for 2011 Equity Incentive Plan†	10	001-35312	September 30, 2011	10.6	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.8	Form of Stock Option Grant Notice and Option Agreement (Director) for 2011 Equity Incentive Plan†	8-K	001-35312	September 18, 2012	10.1	
10.9	Form of Stock Grant Notice and Award Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.1	
10.10	Form of Restricted Stock Unit Grant Notice and Agreement for 2011 Equity Incentive Plan†	8-K	001-35312	September 10, 2013	10.2	
10.11	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A	
10.12	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	
10.13	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	
10.14	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1	
10.15	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1	
10.16	Second Amendment to New-Hire Equity Incentive Plan†	S-8	333-202904	March 20, 2015	99.12	
10.17	Third Amendment to New-Hire Equity Incentive Plan†	S-8	333-210215	March 15, 2016	99.13	
10.18	Fourth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.4	
10.19	Fifth Amendment to New-Hire Equity Incentive Plan	8-K	001-35312	January 18, 2018	10.1	
10.20	Sixth Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2019	10.2	
10.21	Seventh Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	December 6, 2019	10.1	
10.22	Eighth Amendment to New-Hire Equity Incentive Plan†	8-K/A	001-35312	February 25, 2021	10.1	
10.23	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan	10-Q	001-35312	November 12, 2013	10.2	
10.24	2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.1	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.25	First Amendment to the 2017 Equity Incentive Plan†	14A	001-35312	September 11, 2020	App. A	
10.26	Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.2	
10.27	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	
10.28	Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.1	
10.29	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	
10.30	Form of Indemnity Agreement for the Company's executive officers and directors†	10	001-35312	September 30, 2011	10.1	
10.31	Form of Change in Control Agreement for the Company's executive officers†	10-K	001-35312	March 20, 2015	10.16	
10.32	Non-Employee Director Compensation Policy (effective August 18, 2021)†	10-Q	001-35312	November 10, 2021	10.2	
10.33	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18	
10.34	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	
10.35	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	
10.36	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	
10.37	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1	
10.38	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	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.39	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	
10.40	Warrant Agency Agreement, by and between the Company and American Stock Transfer & Trust Company, LLC dated November 27, 2017	8-K	001-35312	November 28, 2017	10.1	
10.41	Form of Warrant Reprice Agreement	8-K	001-35312	June 29, 2018	10.1	
10.42	Consulting Agreement, dated as of January 28, 2019, between the Company and Steve Brandt†	10-K	001-35312	February 21, 2019	10.44	
10.43	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	
10.44	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	
10.45	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	
10.46	Offer Letter, by and between the Company and Nestor Jaramillo, dated April 12, 2019†	10-Q	001-35312	May 9, 2019	10.5	
10.47	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	
10.48	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	
10.49	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	
10.50	Form of Securities Purchase Agreement, dated as of November 4, 2019, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	November 4, 2019	10.1	

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith
		Form	File Number	Date of First Filing		
10.51	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	
10.52	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	
10.53	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	
10.54	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	
10.55	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	
10.56	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	
10.57	Placement Agency Agreement, dated as of May 1, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	May 4, 2020	1.1	
10.58	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	
10.59	Lock-Up and Voting Agreement	S-1/A	333-24145	August 17, 2020	4.2	
10.60	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	
10.61	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	
10.62	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	
10.63	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	

Exhibit Number	Exhibit Description	Incorporated By Reference				Filed Herewith
		Form	File Number	Date of First Filing	Exhibit Number	
10.64	Underwriting Agreement, dated March 17, 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	March 17, 2021	1.1	
10.65	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	
10.66	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	
10.67	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	
21	List of Subsidiaries					X
23	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
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					X

† Indicates management compensatory plan, contract or arrangement.

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

Item 16. Form 10-K Summary

Not Applicable

SIGNATURES

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

Date: March 3, 2022

NUWELLIS, INC.

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

POWER OF ATTORNEY

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

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

Signature	Title	Date
/S/ NESTOR JARAMILLO Nestor Jaramillo	President, Chief Executive Officer and Director (principal executive officer)	March 3, 2022
/S/ GEORGE MONTAGUE George Montague	Chief Financial Officer (principal financial and accounting officer)	March 3, 2022
/S/ JOHN L. ERB John L. Erb	Chairman of the Board and Director	March 3, 2022
/S/ STEVEN BRANDT Steven Brandt	Director	March 3, 2022
/S/ MARIA ROSA COSTANZO Maria Rosa Costanzo	Director	March 3, 2022
/S/ JON W. SALVESON Jon W. Salveson	Director	March 3, 2022
/S/ GREGORY D. WALLER Gregory D. Waller	Director	March 3, 2022
/S/ WARREN S. WATSON Warren S. Watson	Director	March 3, 2022

EXHIBIT 21

SUBSIDIARIES

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

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-215112, 333-216053, 333-216841, 333-221010, 333-221716, 333-229102, 333-235658, 333-235385, 333-236050, 333-237911, 333-238811, 333-230142 and 333-241454), Form S-3 (File No. 333-256797) and Form S-8 (File No. 333-183924, 333-183925, 333-188935, 333-190499, 333-194642, 333-202904, 333-210215, 333-218464, 333-223879, 333-233152, 333-238276, 333-254708 and 333-256432) of Nuwellis, Inc. of our report dated March 3, 2022, relating to the consolidated financial statements, which report expresses an unqualified opinion on the consolidated financial statements for the year ended December 31, 2021, appearing herein.

/s/ Baker Tilly US, LLP
Minneapolis, Minnesota
March 3, 2022

EXHIBIT 31.1

NUWELLIS, INC.
CEO SECTION 302 CERTIFICATION

I, Nestor Jaramillo, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2021 of Nuwellis, Inc.

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

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

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

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

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

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

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

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

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

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

Date: March 3, 2022

/S/ NESTOR JARAMILLO
Nestor Jaramillo
Chief Executive Officer

EXHIBIT 31.2

NUWELLIS, INC.
CFO SECTION 302 CERTIFICATION

I, George Montague, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2021 of Nuwellis, Inc.

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

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

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

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

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

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

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

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

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

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

Date: March 3, 2022

/S/ GEORGE MONTAGUE
George Montague
Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report of Nuwellis, Inc. (the ***"Company"***) on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, Nestor Jaramillo, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 3, 2022

/S/ NESTOR JARAMILLO
Nestor Jaramillo
Chief Executive Officer

EXHIBIT 32.2

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

In connection with the Annual Report of Nuwellis, Inc. (the ***"Company"***) on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, George Montague, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 3, 2022

/S/ GEOR.GE MONTAGUE

George Montague
Chief Financial Officer