



April 2, 2026

Dear Nuwellis Stockholders,

2025 was a year of deliberate transition for Nuwellis as we strengthened the company's operating foundation and sharpened our strategic focus around the cardiorenal continuum. While full-year revenue declined modestly to \$8.3 million, the defining work of the year was the structural progress we made to position the company for more disciplined execution and long-term growth.

During the year, we took a series of intentional steps to simplify the business and concentrate resources where clinical adoption and economic value are most clearly aligned. This included transitioning manufacturing to KDI Precision Manufacturing to improve long-term reliability and scalability, as well as refining our international commercial strategy to focus on markets where demand and commercial conversion are more predictable. We also made the strategic decision to discontinue the REVERSE-HF clinical trial, enabling us to redirect capital and organizational focus toward initiatives with clearer pathways to commercial impact and long-term value creation.

Despite the broader transition underway, we saw encouraging momentum in several of our core clinical categories. Heart Failure and Pediatrics grew 8% and 14% year-over-year, respectively, reinforcing the strength of our value proposition in complex cardiorenal patient populations. Fourth quarter revenue reached \$2.4 million, representing a 4% increase over the prior year period, with U.S. console sales increasing 208% compared to the same quarter in 2024. These results reflect continued expansion of utilization within targeted accounts where clinicians have already adopted our technology.

Innovation remains central to our long-term strategy. During the year we expanded intellectual property supporting our pediatric technology development and benefitted from a National Institutes of Health funding grant to advance this program. These efforts strengthen the foundation of our platform and support our ability to deliver precision fluid management solutions to broader patient populations over time.

As we enter 2026, we are doing so with renewed momentum. We recently acquired Rendiatech Ltd., a privately-held Israeli developer of automated kidney function monitoring technology, expanding our portfolio and enhancing our ability to support clinicians across the cardiorenal continuum. We also welcomed Carisa Schultz as Chief Financial Officer, strengthening our financial leadership as we continue to prioritize disciplined capital allocation, operational consistency, and focused commercial execution.

The work completed in 2025 positions Nuwellis to move forward with greater clarity and purpose. Our focus in the coming year is to translate this strategic alignment into more consistent commercial performance while continuing to expand adoption of our technologies among the physicians and hospital systems we serve.

I would like to thank our employees, physician partners, and shareholders for their continued commitment and support as we work to advance better solutions for patients living with complex cardiorenal conditions.

Sincerely,

John Erb
Chairman and Chief Executive Officer
Nuwellis, Inc.

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

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2025

OR

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
(State or other jurisdiction of incorporation or organization)

68-0533453
(I.R.S. Employer Identification No.)

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

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

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

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

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

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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

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

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

As of June 30, 2025, 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, 2025 closing sale price of \$9.2566 per share) was approximately \$4.6 million.

The number of shares of the registrant's common stock, par value \$0.0001 per share, outstanding as of March 6, 2026 was 2,310,477 shares.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the proxy statement for the 2026 annual meeting of stockholders are incorporated by reference into Part III of this report to the extent described herein.

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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.

Summary of Risk Factors

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

- We will need to raise additional capital to fund our operations beyond the second quarter of 2026. If additional capital is not available, we will have to delay, reduce or cease operations. These factors raise substantial doubt about the Company's ability to continue as a going concern through the next twelve months.
- Our near-term prospects are highly dependent on revenues from a single-product, the Aquadex System. We face significant challenges in expanding market acceptance of the Aquadex System, which could adversely affect our potential sales.
- We have limited history of operations and limited experience in sales and marketing, and we might be unsuccessful in increasing our sales and cannot assure you that we will ever generate substantial revenue or be profitable.
- We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near term. To date, we have been funded by equity financings, and although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.
- We have previously identified two material weaknesses in connection with our internal control over financial reporting which, if not remediated, could adversely affect our business, reputation and stock price.
- We depend on a limited number of customers, the loss of which, or failure of which to order our products in a particular period, could cause our revenues to decline.
- We have limited commercial manufacturing experience and could experience difficulty in producing commercial volumes of the Aquadex System and related components because we depend on third parties for manufacturing.
- We depend upon third-party suppliers, including single-source suppliers, making us vulnerable to supply problems and price fluctuations.
- If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute the Aquadex System effectively and our sales will suffer.
- We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.
- Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales.
- We have experienced and may continue to experience product defects or issues with quality management, which may result in lawsuits for product liability, and could harm our business, results of operations and financial condition.
- We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations.
- If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales will suffer.
- If we fail to comply with federal and state laws regarding off-label use of our products, we could face substantial civil and criminal penalties and our business, financial condition, results of operations, and prospects could be adversely affected.
- If we violate any provisions of the federal Food, Drug, and Cosmetic Act or any other statutes or regulations, we could be subject to enforcement actions by the FDA or other governmental agencies.
- Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.
- We face significant uncertainty in the industry due to government healthcare reform and changes to healthcare regulations.

- We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.
- Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws could subject us to penalties and other adverse consequences.
- Our business could be adversely affected due to risks related to proposed acquisitions and the subsequent integration of such accumulations.
- If we fail to comply with federal and state laws regarding off-label use of our products, we could be subject to regulatory or enforcement actions and face substantial civil and criminal penalties and our business, financial condition, results of operations, and prospects could be adversely affected.
- If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.
- We may not be able to protect our intellectual property rights effectively, which could have an adverse effect on our business, financial condition or results of operations.
- Intellectual property litigation could be costly and disruptive to us.
- If we were unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and system could be adversely affected.
- Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- Changes in U.S. federal government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.
- If we experience an interruption in supply from a material sole-source supplier, our business may be harmed.
- 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.
- Nasdaq has proposed enhanced listing standards, which could adversely affect our ability to maintain our Nasdaq listing and access to capital markets.
- 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 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.
- 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 have a large number of authorized but unissued shares of stock, which could negatively impact a potential investor if they purchased our common stock.
- A more active, liquid trading market for our common stock may not develop, and the price of our common stock may fluctuate significantly.
- We are subject to litigation which could result in a material impact on our business, results of operations, and financial condition.

- Our ability to use U.S. net operating loss carryforwards and other tax attributes might be limited.
- We do not intend to pay cash dividends on our common stock in the foreseeable future.
- 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.
- 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.
- Worldwide economic and market conditions, an unstable economy, a decline in consumer spending levels and other adverse developments, including inflation, could adversely affect our business, results of operations and liquidity, and stock price.
- Changes in spending or budgetary priorities may have a material adverse effect on our business.
- Changes to U.S. tariff and import/export regulations may have a negative effect on our suppliers and/or service providers and, in turn, could have a material adverse impact on our financial condition.

PART I

Item 1. Business

Overview

Nuwellis is dedicated to advancing cardiorenal care by enabling earlier, safer, and more controlled fluid management for patients. The company is focused on developing, manufacturing, and commercializing medical devices used in ultrafiltration therapy, including the Aquadex FlexFlow® and the Aquadex SmartFlow® systems (collectively the “Aquadex System”). The Aquadex SmartFlow® system is indicated for temporary (up to eight hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics.

Please note that selected authors in the citations below are either current consultants to the Company or were previously compensated consultants. Each author typically is required to disclose any actual or potential conflicts of interest at the time they submitted their written manuscript to the potential publication. Dr. Sean Pinney for example, was the principal investigator under the Company’s former REVERSE-HF heart failure clinical study. Additionally, Dr. Maria Rosa Costanzo, joined the Company’s Board of Directors in September 2019, though many of her cited publications preceded her membership on the Board of Directors. She resigned from the Board of Directors on January 21, 2026, which was not the result of any disagreement with Nuwellis regarding its operations, policies, or practices. Since joining the Company’s Board, Dr. Costanzo has declined any equity ownership in the Company, although she has accepted cash remuneration for her Board and Committee participation.

Fluid Overload

Fluid overload, also known as hypervolemia, is a condition in which there is too much fluid in the blood, vital organs, and interstitial space, and generally refers to the expansion of the extracellular fluid volume. Although the body does need some amount of fluid to remain healthy, too much can cause an imbalance and damage to an individual’s health.¹

The signs and symptoms of fluid overload are not always the same in each patient and may vary. However, possible signs and symptoms of fluid overload include pulmonary edema/pleural effusion, peripheral edema, anasarca (swelling of the skin) ascites, jugular vein distention and dyspnea.² Medical conditions or diseases where excess fluid accumulates in the body are heart failure, kidney failure, nephrotic syndrome, cirrhosis, and burn injuries/trauma. Individuals may also suffer from temporary fluid overload following certain surgical procedures, such as cardiac surgery.³ The diagnosis of fluid overload can be made through a variety of tests/exams such as a physical exam (weight, presence of pulmonary rales, and edema), blood chemistry, natriuretic peptides, liver enzymes, hemoglobin and hematocrit, blood volume analysis, and/or bioimpedance analysis.⁴ Fluid overload has a significant association with the combined events of death, infection, bleeding, arrhythmia, and pulmonary edema⁵ and is a leading cause of hospital readmissions with patients suffering from heart failure and patients following cardiac surgery.⁶

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

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

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

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

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

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

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

These dramatic improvements include new medications and new technologies, such as ultrafiltration, to help treat fluid overload. Each year there are over one million heart failure hospitalizations in the United States, and 90% of those hospitalizations are due to symptoms of fluid overload.¹⁴ These patients are hospitalized on average for eight days at a cost of approximately \$24,000, for which reimbursement typically does not cover the full cost.¹⁵

Treatments for Fluid Overload

Diuretics

Treatment for fluid overload has traditionally been achieved through use of oral or loop diuretics which may be accompanied by use of other categories of medications, such as angiotensin-converting enzyme (ACE) inhibitors, sodium-glucose co-transporter 2 (SGLT-2) inhibitors, Aldosterone receptor antagonists (MRAs), beta-blockers, and inotropic drugs. Chronic diuretic use has been associated with increased long-term mortality and hospitalizations in a wide spectrum of chronic systolic and diastolic HF patients.¹⁶ We believe that diuretics, particularly at high doses, may be deleterious to patients. Additionally, between 10-40% of heart failure patients are refractory to diuretics,¹⁷ with diuretic resistance associated with a higher risk of in-hospital worsening of heart failure, increase mortality after discharge, and a three-fold increase in rehospitalization rates.¹⁸ In addition, patients with heart failure and cardiorenal syndrome have diminished response to loop diuretics, making these agents less effective at relieving congestion.¹⁹ Also, long-term use of diuretics has been associated with kidney damage.²⁰ One study found that approximately 40% of heart failure patients have poor diuretic response.²¹ 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.²² Despite treatment with loop diuretics, patients are frequently hospitalized and treated for recurrent symptoms and signs of fluid overload.

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

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

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

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

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

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

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

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

¹⁵ Gheorghide M, et al. *Eur Heart J Suppl*. 2005; 7:B13- 19.

¹⁶ Ahmed A, et al. *Eur Heart J*. 2006 Jun;27(12):1431-9.

¹⁷ Testani JM, Hanberg JS, Cheng S et al. *Circ Heart Fail*. 2016; 9(1): e002370.

¹⁸ Costanzo MR, et al. *J Am Coll Cardiol*. 2017;69(19):2428-2445.

¹⁹ Kamath SA. *Int J of Nephrol*. 2011: 1-6.

²⁰ Felker MG & Mentz RJ. *J Am Coll Cardiol*. 2012;59(24):2145-53.

²¹ Testani JM. *Circ Heart Fail*. 2016 Jan;9(1):e002370.

²² Hoorn EJ & Ellison DH. *Am J Kidney Dis*. 2017;69(1):136-142.

Nearly one half of hospitalized patients with heart failure are discharged with residual fluid excess after receiving conventional diuretic therapies.²³ Additionally, one study found that 24% of such patients were readmitted to the hospital within 30 days of their discharge, and up to 42-50% were readmitted at 90 days and six months respectively.^{24 25} 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.²⁶ We believe that there is an association of chronic loop diuretic therapy and greater resource utilization at hospitals.²⁷ 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 and critical care patients for over 20 years.²⁸ We believe that ultrafiltration is a safe and effective therapy to treat fluid overload and congestion by removing the overload of fluid and congestion by removing extra fluid and salt.²⁹ 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, we believe the data suggests that the therapy provides economic advantages. One hospital's cost analysis demonstrated a total cost savings of \$3,975 per patient when using ultrafiltration as compared to diuretic therapy over 90 days.³⁰

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.^{31 32} Unlike other forms of ultrafiltration, which typically require administration specifically by a nephrologist, the Aquadex System may be prescribed by any physician and administered by a healthcare provider, both of whom have received training in extracorporeal therapies. The Company estimates it has treated more approximately 15,000 patients across all three (3) of our customer categories since it reintroduced the Aquadex System to the U.S. market in 2016.

²³ Orso D, et al. *Eur Rev Med Pharmacol Sci.* 2021 Apr;25(7):2971-2980.

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

²⁵ Thandra A, et al. *Clin Invest.* 2023; 365(2): 145-51.

²⁶ Felker GM, et al. *N Engl J Med.* 2011; 364:797-805.

²⁷ Costanzo MR, et al. *J Am Coll Cardiol.* 2007; 49(6):675-683.

²⁸ Agostoni PG, et al. *J Am Coll Cardiol.* 1993; 21(2):424-431.

²⁹ Kazory A, et al. *Cardiorenal Med.* 2023;13(1)1-8.

³⁰ Costanza MR, et al. *Value Health.* 2018; 21 (Suppl 1):S167.

³¹ SAFE Trial: Jaski BE, et al. *J Card Fail.* 2003; 9(3): 227-231.

³² RAPID Trial: Bart BA, et al. *J Am Coll Cardiol.* 2005; 46(11): 2043-2046.

Benefits of the Aquadex System

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

- In a single center, retrospective analysis of 335 consecutive patients in whom there was follow-up for 12 months, there were 1.74 fewer rehospitalizations for HF in the year following UF when compared to the 12 months preceding UF;³³
- Analysis of an Aquadex program in community-based regional hospitals with 30 patients showed refractory acute decompensated heart failure (ADHF) patients benefited from significant volume loss (mean loss of 9.40 + 4.55L) and weight reduction (mean decrease of 7.40kg) along with stable renal function and remarkable clinical benefit as well as a statistically significant reduction in the ADHF rehospitalization rate at 60 days (p=0.013).³⁴
- A re-appraisal of the AVOID-HF trial (n=224 patients), including an additional 31 adjudicated events to complete the dataset, demonstrated that patients treated with adjustable ultrafiltration (AUF) had a 60% reduction in heart failure events at 30 days compared to intravenous diuretics (p=0.014) and significantly fewer HF hospitalizations at 30 days (p=0.032).³⁵
- Rehospitalizations at 30 days with Aquadex were 12.4% compared with the national average at 30 days of 24%;
- Reduces length of hospital stay when initiated early, resulting in average savings of \$3,975 (14%);³⁶
- Stabilizes or improves cardiac hemodynamics;^{37 38}
- Is safe, easy-to-use, and flexible in application;
- Provides complete control over rate and total volume of fluid removed by allowing a medical practitioner to specify the amount of fluid to be removed from each individual patient;
- Can be performed via peripheral or central venous access;
- Predictably removes excess isotonic fluid (extracts water and sodium while sparing potassium and magnesium; decrease risk of electrolyte abnormalities);^{38 40}
- Results in no significant changes to kidney function;⁴¹
- Uses continuous hematocrit monitoring and SvO₂ sensors to provide guided-therapy ultrafiltration;⁴²
- Following ultrafiltration, neurohormonal activation is reset toward a more physiological condition and diuretic efficacy is restored;⁴³
- Provides highly automated operation with only one setting required to begin therapy;
- Utilizes a single-use, disposable auto-loading blood filter circuit that facilitates easy set-up; and
- Has a built-in console that guides the medical practitioner through the setup and operational process.

Components of the Aquadex System

The Aquadex System consists of:

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

³³ Watson R, et al. *Am Heart J Plus: Cardiol Res & Pract* 24. 2022; 1-6.

³⁴ Chinta et al. *Current Problems in Cardiology*. 49 (2024) 102716.

³⁵ Pinney et al. *J Am Coll Cardiol HF*. Feb 19, 2025.

³⁶ Costanza MR, et al. *Value Health*. 2018; 21 (Suppl 1):S167.

³⁷ Boga M, et al. *Perf*. 2000; 15:143-150.

³⁸ Kiziltepe U, et al. *Ann Thorac Surg* 2001;71:684-93.

³⁹ Kazory A, et al. *Cardiorenal Med*. 2023;13(1)1-8.

⁴⁰ Agostoni PG et al. *J Am Coll Cardiol*. 1993;21(2):424-31.

⁴¹ Kazory A, et al. *Cardiorenal Med*. 2023;13(1)1-8.

⁴² Starr MC, et al. *Pediatric Nephrology*. 2024; 39(2):597-601.

⁴³ Costanzo MR, et al. *J Am Coll Cardiol*. 2005; 46(11): 2047-51.

Our Market Opportunity

The Aquadex System is used for the treatment of patients suffering from fluid overload who have failed medical therapy including diuretics. We are currently focusing our commercial activities in three primary clinical areas where fluid overload is prevalent: pediatrics, critical care, and heart failure.

Pediatrics

Many of the conditions and procedures faced by adult patients also occur in pediatric patients, such as cardiac surgery, organ transplants, heart failure, nephrotic syndromes 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.⁶⁷ Fluid overload drives pediatric morbidity and mortality risk in critically ill patients. In one pediatric study, a 3% increase in mortality was observed for every 1% increase in fluid overload, and children who are more than 20% fluid overloaded have an odds ratio for mortality of 8.5 compared to children who are less than 20% fluid overloaded.^{68 69}

The Company believes that the total U.S. pediatric market for fluid overload is approximately \$160 million.⁷⁰ In 2025, the Company derived approximately 40% of its revenue from the treatment of pediatric patients.

While the Aquadex System is only FDA-cleared for the treatment of pediatric patients weighing 20 kg or more, the Company is aware that many children's hospitals in the U.S. are modifying the way that the Aquadex System is used in a manner that is deemed to be off-label by the Company and the FDA in order to provide dialysis to neonates and other premature infants who weigh less than 20 kg and who were born either without kidneys, inborn errors of metabolism or without normal kidney function. These patients typically have very few other treatment options given the large extracorporeal blood volume required by standard dialysis machines (58ml for Baxter HF20 device), the need for blood priming of the dialysis circuit, vasoactive medications to support hemodynamics, and the use of large bore dialysis catheters. By comparison, the Aquadex extracorporeal blood volume is only 35 ml, with low blood flow range of 10-40 ml/min, and smaller alternative catheters can be used.

It is because of this unmet medical need that the Company has undertaken the development of a dedicated Continuous Renal Replacement Therapy ("CRRT") device intended for patients weighing above 2.5 kg and under 20 kg. See - Product Development Activities below.

⁶⁷ Jayaprasad, N. *Heart Views*. 2016; 17(3): 92-99.

⁶⁸ Sutherland SM, et al. *Am J Kidney Dis*. 2010; 55(2):315-25.

⁶⁹ Gillespie RS, et al. *Ped Nephro*. 2004; 19(12):1394-99.

⁷⁰ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

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, extracorporeal 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.⁵⁶ Cardiac surgery is associated with a degree of fluid overload due to cardiopulmonary bypass.⁵⁷ Intravenous fluid therapy is an integral treatment for patients undergoing surgery and in critical care units.⁵⁸ Fluid overload in post-cardiac surgery can readily occur because surgery can affect the pumping actions of the heart, leading to postoperative hemodynamic instability.⁵⁹ The condition often remains symptomless for several days until clinical symptoms become apparent, when treatment is almost always too late and ineffective.⁶⁰

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.⁶¹ As many as 80% of cardiac surgery patients may have stage one or greater cardiac-surgery-associated acute kidney injury (CSA-AKI).⁶² In the recent publication A Turnkey Order Set for Prevention of CSA-AKI the new CSA-AKI Guidelines suggest the avoidance of nephrotoxic agents including loop diuretics and considering the use of ultrafiltration during post-surgery recovery.⁶²

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.⁶³ It is estimated that 13.5% of post-cardiac surgery patients are readmitted due to fluid overload within 30 days of discharge. Research has been recently published demonstrating the value of ultrafiltration in high-risk coronary artery bypass grafting surgery.⁶⁴ It is also encouraging to see ultrafiltration being recommended for cardiac surgery patients who are unresponsive to diuretics in a recently published turnkey order set proposed by the Enhanced Recovery After Surgery (“ERAS”) Society consensus guidelines.⁶²

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

The Company believes the total U.S. critical care failure market is approximately \$900 million.⁶⁵ In 2025, the Company derived approximately 32% of its revenue from the treatment of critical care patients.

⁵⁶ <https://idataresearch.com/new-study-shows-approximately-340000-cabg-procedures-per-year-in-the-united-states/>.

⁵⁷ Kruger A et al. *J Cardiovasc Dev Dis.* 2023;10(6):263-78.

⁵⁸ Bowdish ME, et al. *Ann Thorac Surg.* 2021;111(6):1770-1780.

⁵⁹ Xu J, et al. *Medicine.* 2015;94(33):e1360.

⁶⁰ Xu J, et al. *Medicine.* 2015;94(33):e1360.

⁶¹ Crawford TC, et al. *Ann Thorac Surg.* 2017;103:32-40.

⁶² Engelman D, et al. *Ann Thorac Surg.* 2023;115:11-5A

⁶³ Iribane A, et al. *Ann Thorac Surg.* 2014;98:1274-80.

⁶⁴ Beckles DL et al. *J Card Surg.*2022; 37: 2951-57.

⁶⁵ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

Heart Failure

Heart Failure

Heart failure is a syndrome that can have an acute onset or is a progressive disease caused by impairment of the heart's ability to pump blood to the various organs of the body. Patients with heart failure and fluid overload commonly experience shortness of breath, fatigue, difficulty exercising and swelling of the legs. The heart becomes weak or stiff and enlarges over time, making it harder for the heart to pump the blood needed for the body to function properly. The severity of heart failure depends on how well a person's heart pumps blood throughout the body.⁴⁸

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 of lost fluid.⁴⁹ This clinical evidence from the ADHERE registry shows patients are discharged too early, while still showing evidence of fluid overload.

As a result of not fully having their fluid imbalance properly addressed prior to discharge from the hospital, patients are frequently being readmitted, with one study showing 30-day readmission rates of 24% and six-month readmission rates of 44%.^{50 51}

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.⁵² As the population ages, healthcare expenditures are expected to increase substantially.⁵³ Therefore, therapies aimed at treating congestion and fluid overload are essential from a patient care and healthcare economics perspective.

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

Hospitals in the United States also face potential penalties for heart failure readmissions. As part of the Patient Protection and Affordable Care Act of 2012, as amended (the "Affordable Care Act"), Medicare instituted the Hospital Readmissions Reduction Program, which penalizes hospitals with high 30-day readmission rates for heart failure and other common diseases and procedures. This penalty can be as high as 3% of reimbursement for all Medicare admissions. Technologies that help reduce readmissions, such as the Aquadex System, can help hospitals mitigate these penalties.⁵⁴

The Company believes the total U.S. heart failure market is approximately \$1 billion for inpatient therapy and is approximately \$770 million for outpatient therapy.⁵⁵ Roughly 17% of its 2025 revenue was derived from the treatment of heart failure patients.

⁴⁴ Shah, K, et al. *J Am Coll Cardiol*. 2017 Nov, 70 (20) 2476-2486.

⁴⁵ Bozhurt B, et al. *J Card Fail. J Card Fail*. 2023; 29(10): 1412-42.

⁴⁶ Benjamin EJ, et al. *Circ*. 2017;135:00-00. (e378).

⁴⁷ Fonarow GC, et al. *Rev Cardiovasc Med*. 2003; 4: s21-30.

⁴⁸ Arrigo M et al. *Nat Rev Dis Primers*. 2020; 6(16):1-15.

⁴⁹ Fonarow et al. *Rev Cardiovasc Med*. 2003;4: Suppl 7:S21-30.

⁵⁰ Costanzo MR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445.

⁵¹ Sax D, et al. *J Card Fail*. 2022; 28(10): 1545-59.

⁵² Voigt J, et al. *Clin Cardiol*. 2014;37(5): 312-321.

⁵³ Heidenreich PA, et al. *Circ Heart Fail*. 2013;6(3):606-619.

⁵⁴ McIlvennan C et al. *Circ*. 2015; 131(20): 1796-1803.

⁵⁵ See Appendix to Company Investor Presentation filed with the SEC on Form 8-K/A, dated January 9, 2024.

Growing Clinical Evidence

In December 2025, the Journal of Clinical Nephrology published *Diversifying Aquapheresis in Critical Care: An Institutional Experience* which highlights data using the Aquadex System at Lenox Hill Hospital in New York City. The retrospective review spans therapy use from January 2018 through July 2024, and captures data for 69 patients in various critical care environments including Cardiothoracic ICU, Medical ICU, Surgical ICU, and Cardiac ICU.⁹³ Each patient had a component of kidney dysfunction: oliguric acute kidney injury (39), decompensated CHF (10), post cardiovascular surgery/intervention (10), optimization pre-cardiovascular surgery/intervention in end-stage renal disease (ESRD) patients (7), septic shock with non-oliguric AKI and volume overload (2), transfusion associated circulatory overload or TACO (1).⁹³ Conclusions from the review include; The average UF volume was 6.4 L per patient, with an UF rate of 82 mL/h.⁹³ Aquapheresis is used as an adjunct therapy with traditional Renal Replacement Therapies (RRT) in 59% of cases, as well as 64% of patients received vasoactive medications during therapy.⁹³ Aquapheresis was shown to effectively and predictably remove significant volume across diverse patient populations in Critical Care environments.⁹³

In March 2025, data from the ULTRA-PEDs multicenter, observational retrospective and prospective pediatric registry was presented at the Advances in Critical Care Nephrology's AKI & CRRT meeting. The Company launched the registry in November 2020 and conducted the registry at seven clinical sites prior to closure in October 2023 with one patient enrolled. The results indicated that the Aquadex[®] device can provide both standard ultrafiltration and modified continuous veno-venous hemofiltration (CVVH) in children with end-stage renal disease (ESRD) or acute kidney injury (AKI) and Fluid Overload (FO) across a wide weight spectrum. Two thirds of procedures lasted for the intended duration, and very few patients could not tolerate the Aquadex[®] procedure.^{71, 72}

In January 2023, we began designing an IDE clinical study for the Company's dedicated pediatric device currently under development. The design was reviewed with FDA in May 2023 and the study is anticipated to begin enrollment in 2027.

In December 2021, we launched the REVERSE-HF prospective, multicenter, randomized controlled trial (RCT) to evaluate ultrafiltration compared to IV diuretics in patients with heart failure (HF). Seventeen clinical sites nationwide were activated to enroll patients in this RCT and fifteen sites have contributed to patient enrollment, which began in June 2022. The Company terminated the study in July 2025 as a cost saving measure: the decision to end the study was unrelated to efficacy, product performance or patient safety concerns. This decision reflects the Company's strategic commitment to prioritize resources in areas demonstrating the greatest potential for patient impact and business growth, namely, outpatient heart failure, pediatric, and critical care. The Company anticipates it will save approximately \$4.0M over the next 2.5 years by terminating the REVERSE-HF clinical trial prior to reaching expected enrollment.

⁷¹ Starr et al. *Epidemiology and Outcomes of Children with AKI or ESKD treated with Aquadex*. AKI & CRRT meeting; March 2025, San Deigo, CA.

⁷² Goldstein et al. *Aquadex Technical Performance in Children with AKI or ESKD*. AKI & CRRT meeting; March 2025, San Deigo, CA.

⁹³ Pino Domenech E, Moses AA, Rosenstock JL, De Vita M. *Diversifying aquapheresis in critical care: An institutional experience*. Clin Nephrol. 2025 Dec 11.

In February 2025, a re-appraisal of the complete dataset, including an additional 31 adjudicated events, from the AVOID-HF trial, demonstrated that patients treated with adjustable ultrafiltration (AUF) had a 60% reduction in heart failure events (HF) at 30 days ($p=0.014$) compared to adjustable intravenous diuretics (ALD) and significantly fewer HF hospitalizations at 30 days ($p=0.032$).⁷³ Additionally, a hierarchical composite endpoint of 30-day cardiovascular (CV) mortality, HF events (including HF rehospitalization, unscheduled outpatient or emergency room treatment with intravenous loop diuretics, vasoactive drugs, or ultrafiltration) and change in quality of life was evaluated using the Finkelstein-Schoenfeld win ratio (WR) method. In the composite outcome, there were two CV deaths within 30 days. AUF won in 71.0% of the HF event-related paired comparisons (versus 29.0% for ALD) and in 53.4% of quality-of-life comparisons (versus 46.6% for ALD), resulting in a WR = 1.43 ($p=0.056$) favoring ultrafiltration.⁷³ This updated evidence further suggests that AUF may be more effective than ALD at reducing HF events and HF rehospitalizations and shows a clear trend toward a sustained clinical benefit when evaluating a holistic composite outcome including CV mortality, HF events and quality of life.⁷³ The re-analysis was also presented as a Late Breaking Clinical Trial podium presentation at the Technology and HF Therapeutics Conference in March 2024.⁷⁴

A former reanalysis of the original AVOID-HF dataset, using a similar WR composite method, was presented at the Annual Scientific Session of the Heart Failure Society of America in September 2022, “*Revisiting The Aquapheresis Versus Intravenous Diuretics And Hospitalizations For Heart Failure (AVOID-HF) Trial: Further Evidence Supporting Aquapheresis To Reduce Heart Failure Events,*” exploring CV mortality within 90 days and HF events within 30 days. This WR analysis also yielded results favoring ultrafiltration, demonstrating that AUF is safe and more effective than ALD in reducing CV mortality and subsequent HF events for hospitalized heart failure patients.⁷⁵

In June 2024, analysis of an Aquadex program, *Outcomes of Ultrafiltration in community-based hospitals*, showed diuretic refractory acute decompensated heart failure (ADHF) patients benefited from significant volume loss and weight reduction along with stable renal function and remarkable clinical benefit.⁷⁶ All 30 patients treated over the first-year cohort were included in a retrospective analysis that demonstrated Aquadex therapy provided a statistically significant reduction in heart failure rehospitalization rate at 60 days ($p=0.013$) and numerically fewer ADHF readmissions at 30 days from UF initiation compared to the pre-UF era.⁷⁶ The study demonstrated that a successful Aquadex program is reproducible and can be coordinated by general cardiologists without the need for a dedicated heart failure unit.⁷⁶

In a November 2023 retrospective case series and literature review conducted by The Mount Sinai Hospital, “*Utilization of aquapheresis among hospitalized patients with end-stage liver disease: A case series and literature review,*” utilization of ultrafiltration from January 2020 through July 2023 in patients with decompensated cirrhosis in the intensive care unit (ICU) found that the introduction of ultrafiltration earlier in a patient’s hospital course may reduce the risk of kidney injury and diuretic-induced electrolyte derangement and reduce the risk of development of sequential organ failures in patients with decompensated cirrhosis.⁷⁷

In September 2023, a third-party, single-center case study review of pediatric patients showed the Aquadex System successfully treated small patients without hemodynamic instability or other complications, demonstrating that therapy is an effective treatment option for fluid overload. Patient treatment was guided with the continuous hematocrit monitoring function built within the Aquadex System, supporting safe and effective fluid removal in critically ill pediatric patients.⁷⁸

In December 2022, a third-party, single-center, real-world retrospective study of 335 consecutive patients treated with the Aquadex FlexFlow® System, “*Ten Year Real World Experience with Ultrafiltration for the Management of Acute Decompensated Heart Failure,*” compared previous randomized controlled clinical trials with ultrafiltration and demonstrated that ultrafiltration compares favorably in reducing heart failure rehospitalizations (2.14 hospitalizations per year before Aquadex versus 0.4 hospitalizations per year one year after Aquadex), renal function response, and weight/volume loss.⁷⁵ The study found ultrafiltration to be safe with regard to renal function despite the cohort in this study being sicker than those studied in other clinical trials, and that ultrafiltration can be a safe and effective strategy for decongestion in clinical practice wherein the benefits outweigh the potential risks of kidney dysfunction requiring hemodialysis and major bleeding events.⁷⁹

In February 2022, a third-party retrospectively reviewed study, “*The Use of Ultrafiltration as a fluid management strategy for High-Risk Coronary Artery Bypass Grafting,*” concluded that ultrafiltration is a safe and effective modality to manage fluid balance in a patient population with relatively high Society of Thoracic Surgery (“STS”) scores, but a prospective multicenter study would be warranted in this patient cohort.⁷⁶

Additionally, another peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients⁸⁰ and a cost analysis demonstrated that compared to diuretics, ultrafiltration resulted in a total cost savings of 14.4% at 90 days due to reduced readmissions.⁸¹

⁷³ Pinney et al. Ultrafiltration for Management of Decompensated Heart Failure: A re-appraisal of AVOID-HF. *J Am Coll Cardiol HF*. Feb 19, 2025.

⁷⁴ Pinney S, et al. Podium Presentation from Technology and HF Therapeutics Conference; March 2024, in Boston, MA.

⁷⁵ Pinney S, et al. Poster from Heart Failure Society of America Meeting; October 2022; Washington, DC.

⁷⁶ Chinta et al. *Current Problems in Cardiology*. 49 (2024) 102716.

⁷⁷ Crismale, J. et al. *Clinical Transplantation*. 2024; 38:e15221.

⁷⁸ Starr MC, et al. *Pediatric Nephrology*. September 2023.

⁷⁵ Watson R, et al. *Am Heart J Plus: Cardiol Res & Pract* 24. 2022; 1-6.

⁷⁹ Beckles D. et al. *J of Card Surg. Fail*. 2022; 37(10): 2951-2957.

⁷⁷ Kazory et al. *Cardiorenal Med*. 2023;13:1-8.

⁸¹ Costanzo MR, et al. *J of Med Econ*. 2019; 22(6): 577-583.

Jain et al. pooled data from seven randomized controlled trials of ultrafiltration with a total of 771 patients and concluded that extracorporeal ultrafiltration is associated with more efficient fluid and sodium removal compared with medical therapy, hence leading to a reduction in readmission rates and a potential salutary impact on financial burden associated with the care of heart failure patients.⁸² Wobbe et al pooled data from eight randomized controlled trials enrolling 801 participants and studied the effectiveness of ultrafiltration compared to diuretics, demonstrating ultrafiltration increases fluid removal (difference in means 1372.5 mL; $p < 0.001$) and weight loss (difference in means 1.592 kg; $p < 0.001$), lower incidence of worsening heart failure (OR 0.63; $p = 0.022$) and rehospitalization for heart failure (OR 0.54; $p = 0.003$) suggesting ultrafiltration is a safe and effective treatment option for volume-overloaded heart failure.⁸³

One 2019 peer-reviewed paper reported on a multicenter, retrospective case series of children who received kidney replacement therapy (“KRT”) with an ultrafiltration device.⁸⁴ Patients were grouped according to weight and primary disease state (e.g. kidney, cardiac or other) and received one of three treatment modalities. The study found that of the 72 patients who weighed less than 10 kg, 43 or 60% survived to the end of therapy or transitioned to another modality of kidney support, and 23 or 32% survived to hospital discharge. Among patients who weighed between 10-20 kg, 13 or 100% survived to the end of KRT treatment. Among patients who weighed more than 20 kg, 33 or 97% survived to KRT discontinuation and 23 or 68% survived to hospital discharge.⁸⁴

⁸² Jain et al. *Heart Fail Rev.* 2016.

⁸³ Wobbe et al. *Heart Fail Rev.* 2021; 26:577–585.

⁸⁴ Menon S, et al. *Clin J Am Soc Nephrol.* 2019;14(10):1432-1440.

Product Development Activities

As we expand our commercialization efforts in the pediatric market, we are developing a dedicated CRRT device, branded Vivian, to address the unmet and specific needs of pediatric patients weighing 2.5kg and above who do not have functioning kidneys and who need kidney replacement therapy for survival. Approximately 10,300 children suffer from AKI, of these, over 1800 are neonates.⁸⁵ Funded in part by a \$1.7 million grant from the National Institute of Health, (“NIH”) the Company completed preliminary engineering testing for its dedicated pediatric system in the fourth quarter of 2023. The Company intends to submit an Investigational Device Exemption (“IDE”) with the FDA in the second quarter of 2028, with U.S. commercialization of this product expected in the first quarter of 2030. In 2025, the NIH awarded a second grant for \$3 million over a three (3) year period to further support the Company development efforts related to Vivian.

⁸⁵ Sutherland et al. *Clin J Am Soc Nephrol.* 2013 Oct 7; 8(10): 1661–1669.

Our Strategy

Nuwellis is dedicated to advancing cardiorenal care by enabling earlier, safer, and more controlled fluid management for patients. We provide healthcare professionals with a reliable, predictable, and easy-to-use mechanical pump and filtration system to remove excess fluid from fluid overloaded patients. We believe that our technology will provide a competitive advantage in the fluid management market by providing improved clinical benefits and reducing the cost of care relative to other treatment alternatives.

Our strategic focus is to demonstrate a strong business model by driving revenue growth. Growing revenue is the key metric employees, stockholders and potential investors will use to judge our performance. Our field-based employees include both sales representatives and clinical education specialists in ten sales territories in the United States. 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, as well as the outpatient setting. With our FDA 510(k) clearance for use in pediatric patients weighing 20kg or more, we have expanded our commercialization efforts to treatments for pediatric patients.

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

Pediatrics: Ultrafiltration is used by physicians to treat fluid overload in various conditions in pediatric patients, including heart failure, cardiac surgery,⁸⁶ ECMO therapy,⁸⁷ solid organ transplantation,⁸⁸ and kidney replacement therapy for neonatal patients. In February 2020, the Company received FDA 510(k) clearance for the Aquadex System to include pediatric patients who weigh 20kg or more. With this clearance, we expanded our commercialization efforts to include promotion to physicians and hospitals who treat this pediatric population, and we are invested in the development of new clinical evidence around use of ultrafiltration in pediatric patients, including the ULTRA-Peds pediatrics registry that concluded in 2023. We are also investing in the development of a new dedicated pediatric CRRT device, to further address the needs of the pediatric population, and in clinical studies supporting the use of this device.

Heart Failure Inpatients: Heart failure patients suffering from fluid overload may be treated in an inpatient setting, such as a hospital cardiology clinic or ICU. 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 analysis using the data collected via the REVERSE-HF ultrafiltration and IV diuretics comparison study, which was terminated early for reasons not related to patient safety.

Heart Failure Outpatients: Further, we intend to expand the use of the Aquadex System with heart failure patients in the outpatient setting, such as an infusion clinic or hospital outpatient department (e.g., observation unit). On January 1, 2022, the American Medical Association granted a new and dedicated Category III Current Procedural Terminology (CPT) code, 0692T, for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver ultrafiltration to adult and pediatric patients weighing more than 20kg (both inpatient and outpatient). In addition, on January 1, 2025, the CPT code was associated with a level II Ambulatory Payment Code (APC) code that provides higher reimbursement per day 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, which may relieve some of the growing pressure on hospital systems and improve hospital economics and patient quality of life. Continued focus on driving positive coverage policies for various targeted private payers will be an ongoing strategy for the Company.

On August 7, 2025, the Company announced its decision to exit international operations in all but four (4) foreign jurisdictions: Singapore, Hong Kong, Israel and Brazil, in order to focus on the U.S. market—where the Company is seeing the strongest growth and clinical demand. This strategic realignment supports Nuwellis’ core business strategy: investing in the markets driving revenue growth. With expanding traction in U.S. cardiac surgery and pediatric programs, and a rising opportunity in the hospital-based outpatient space, the Company is streamlining to prioritize investment in markets where it can have the most immediate and long-term impact.

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 had 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. In 2025, project work started for a large Aquadex System software upgrade to enhance device performance, improve end user experience, and add features and functions to better meet the critical care and pediatric patient populations for therapy delivery. The upgrade is expected to be released to customers in 2026. As we expanded our commercialization efforts in the pediatric market, we developed a CRRT console to address the unmet and specific needs of pediatric patients who do not have functioning kidneys and need kidney replacement therapy for survival.

⁸⁶ Elliott MJ. *Ann Thorac Surg*. 1993;56:1518-22.

⁸⁷ Selewski DT, et al. *Crit Care Med*. 2012; 40(9): 2694-2699.

⁸⁸ Riley AA. *BMC Nephrology*. 2018; 19:268-80.

Sales and Marketing

As of December 31, 2025, we had 24 full-time employees in sales and marketing. We have ten sales territories in the United States. Our U.S. field salesforce includes sales managers, account managers and clinical education specialists who provide training, technical and other support services to our customers. Following the acquisition of the business associated with the Aquadex System (the “Aquadex Business”) from Baxter in August 2016, our direct salesforce was focused initially on re-engaging hospital accounts that had ordered Aquadex blood sets in prior years, re-educating customers on ultrafiltration therapy, and assessing each hospital’s use of the Aquadex System to gain additional opportunity for increased utilization, primarily in heart failure. In 2018, we expanded our commercialization efforts to include post-cardiac surgery. In September 2019, we realigned our salesforce to further focus on the acute needs of fluid overloaded patients in the critical care setting, while still supporting heart failure. We expanded our commercialization efforts to include pediatrics, following receipt of FDA 510(k) clearance of the Aquadex System to include pediatric patients who weigh 20 kg or more in February 2020.

In the United States, our target customers for the Aquadex System include healthcare systems and academic hospitals specializing in advanced treatment of chronic heart failure and/or critical care patients. With the FDA 510(k) clearance of the Aquadex SmartFlow® system for patients weighing over 20kg, we are also targeting pediatric hospitals. Our largest customer represented 13.7% of our 2025 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.⁸⁹ No differences were noted in symptoms of dyspnea between the groups. In addition, through 90 days of follow-up, the ultrafiltration group experienced significantly fewer re-hospitalizations and unscheduled medical visits for heart failure, while renal function assessed by serum creatinine level was not significantly different between the groups.⁸⁹

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. We believe that the trial results were impacted by centers unfamiliar with the use of ultrafiltration therapy; that more than one third of the ultrafiltration group received diuretics instead of ultrafiltration; ultrafiltration rates were fixed rather than utilizing adjusted ultrafiltration rates according to patient characteristics, whereas diuretic doses were titrated based on urine output, and that the diuretic regimen employed was not representative of standard-of-care.⁸⁶ 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.⁹⁰ 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.⁹¹ The data suggests that the benefits of decongestion may outweigh modest or transient increases in serum creatinine during ultrafiltration. Thus, we believe that a change in creatinine should not dissuade the use of ultrafiltration.

⁸⁹ Costanzo MR, et al. *J Am Coll Cardiol*. 2007; 49(6):675-683

⁸⁶ Urban S, et al. *Adv Clin Exp Med*. 2021;30(7):737-746.

⁹⁰ Grodin JL, et al. *Eur J of Heart Fail*. 2018;20(7):1148-1156.

⁹¹ Rao VS, et al. *Circ Heart Fail*. 2019;12 (6):e005552.⁹² Costanzo MR, et al. *JACC: Heart Failure*. 2016;4(2):95-105.

Disparate results between UNLOAD and CARRESS led to initiation of the AVOID-HF trial, designed to prospectively address the question of patient outcomes when treated with ultrafiltration versus intravenous diuretics for acute decompensated heart failure (HF), which was initiated by Baxter International, Inc. (“Baxter”) in 2016.⁹² 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, for business reasons unrelated to patient outcomes or device safety. Despite being underpowered, the results of AVOID-HF indicated distinct trends toward a greater amount of time free of heart failure events within 90 days, favoring the ultrafiltration group over diuretics with 62 days to first event for ultrafiltration patients and 34 days to first event for diuretic patients. In addition, pre-specified secondary endpoints demonstrated significant reductions in heart failure rehospitalizations and days in the hospital and cardiovascular events at 30 days. No significant differences were observed in creatinine level between the groups during treatment and up to 90 days following treatment. In totality, AVOID-HF recapitulated the results of both UNLOAD and CARRESS while providing evidence that had AVOID-HF been followed to completion, it is our belief that the trial would likely have met its primary endpoint of improved outcome in acute decompensated heart failure patients.

Research and Development

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

In 2021 we initiated a product development project designed to enhance the functionality of the hematocrit sensor that is part of the Aquadex console. The sensor effort was completed in 2025 and will move into production consoles in 2026.

In 2021, we also initiated a product development project to develop a pediatric continuous renal replacement therapy (CRRT) device. We successfully completed functional system prototypes in 2022 and preliminary engineering testing in 2023. The Company intends to submit an IDE with the FDA in the second quarter of 2028 for this pediatric CRRT device, with commercialization expected in the United States in the first quarter of 2030 following completion of the IDE study.

Manufacturers and Suppliers

We manufactured the Aquadex System at our 23,000 square foot facility in Eden Prairie, Minnesota through the fourth quarter of 2025. We had manufactured the Aquadex SmartFlow® console and blood circuits since the Aquadex System’s development in 2019. We purchased parts and components for the Aquadex System from third-party manufacturers and suppliers.

On May 12, 2025, the Company announced it had finalized an agreement with KDI Precision Manufacturing to support the next phase of Nuwellis' growth. The Company made a contractual payment of \$240,000 on July 15, 2025 to initiate the transfer of the manufacturing process to KDI. This strategic relationship is expected to expand Nuwellis' manufacturing capabilities, streamline operations, and enhance the company's ability to deliver high-quality products to healthcare providers and patients. Under the agreement, KDI has assumed assembly responsibilities for the Aquadex SmartFlow® Console, AquaFlexFlow® Blood Circuits, and dELC® Catheters. To ensure a seamless transition and protect product expertise, Nuwellis assembly employees were hired by KDI. Sales, customer service, product design, and post-market surveillance will continue to reside within Nuwellis. During the third quarter of 2025, console manufacturing and calibration of consoles were moved to the KDI facility. As of October 20, 2025, all circuit and catheter manufacturing personnel had transitioned to KDI.

Intellectual Property

We have employed a patent strategy in order to establish an intellectual property portfolio through which we seek to protect our system and technology. We estimate that most of our currently issued U.S. patents will expire by 2027.

In addition to the licensed patents, we have ten (10) company-owned patents, including two (2) patents issued within the last two years.

A number of Nuwellis issued patents in the United States are directed to the C-Pulse® Heart Assist System (the "C-Pulse System") for treatment of Class III and ambulatory Class IV heart failure of which the last expiring issued U.S. patent has a term to 2026. Given the strategic refocus away from the C-Pulse System and toward the Aquadex System, we have chosen to limit the maintenance of issued C-Pulse System.

In addition, we have four pending patent applications in the United States unrelated to our dedicated pediatric device in development.

We also have filed a family of patent applications related to our dedicated pediatric device in development. This has resulted in four (4) issued United States patents, five (5) pending United States patent applications and a pending international patent application filed under the Patent Cooperation Treaty.

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.

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

Competition

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

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

Third-Party Reimbursement

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

While the agency responsible for administering the Medicare program, the Centers for Medicare and Medicaid Services (CMS), has not issued a formal national coverage determination for ultrafiltration using the Aquadex System, there is established CMS reimbursement in absence of the policy. On January 1, 2022, a new and dedicated Category III Current Procedural Terminology (CPT) code, 0692T, became effective for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver ultrafiltration to adult and pediatric patients weighing more than 20kg. On January 1, 2025, the CPT code was reassigned to a level II Ambulatory Payment Classification (APC) code that provides substantial daily reimbursement for therapeutic ultrafiltration administered in the outpatient setting. Additionally, 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 as well, and patients and providers may seek insurance coverage on a case-by-case basis. Nuwellis has engaged a third-party reimbursement consulting firm to assist customers with the necessary tools to build billing and coding into hospital systems, advising on pre-authorization and pre-approvals, claims processing, denials, and local payor contracts per institution. The capability to support reimbursement efforts and claims with the existing 0692T code will pave the way for Nuwellis to expand use ultrafiltration with Aquadex to private payor approved procedures in the future.

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

Government Regulations

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

United States

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

Unless an exemption applies, each medical device we intend to commercially distribute in the U.S. will require premarket authorization from the FDA, most likely in the form of 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. FDA has 90 days by statute to review a 510(k) notice once it has been accepted, though this clock is paused upon issuance of a request for additional information from the sponsor (usually around day 60). After a device has received 510(k) clearance for a specific indication for use, any modification to that device that “could significantly affect its safety or effectiveness,” such as a significant change in the design, materials, or method of manufacture, or which represents a “major change” to the intended use of the device, requires a new 510(k) clearance prior to being implemented. The determination as to whether a new 510(k) is needed is initially left to the manufacturer; however, the FDA may evaluate the regulatory status of the modified at any time and, if it disagrees with the sponsor’s determination that a new 510(k) was not needed, may require the manufacturer to cease marketing the modified device until 510(k) clearance is received.

The Aquadex FlexFlow system was first granted FDA 510(k) clearance for commercial use on June 3, 2002. On February 24, 2020, we received 510(k) clearance of the Aquadex FlexFlow System 2.0 (“SmartFlow®”) (K192756) system for use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics. The Aquadex SmartFlow incorporates functions for physicians to use during an Aquadex therapy to more precisely determine the amount of excess fluid to be removed, the rate of ultrafiltration, and when to stop therapy as dry weight is approached.

Clinical Trials. Clinical trials may be required to support a marketing application for certain device. All clinical trials must be conducted in accordance with regulations and requirements collectively known as “Good All clinical trials must be conducted in accordance with “Good Clinical Practices” – including but not limited to the FDA’s IDE regulations – which describe the conduct of clinical trials with medical devices. They also prohibit promotion, test marketing or commercialization of an investigational device and any representation that such a device is safe or effective for the purposes being investigated. Good Clinical Practices also include the FDA’s regulations for institutional review board approval and for protection of human subjects (such as informed consent), as well as disclosure of financial interests by clinical investigators. Required records and reports are subject to inspection by the FDA. Premarket clinical trials require submission of an application for an investigational device exemption (IDE) to the FDA prior to commencing the trial if the device poses a “significant risk” as defined in the FDA regulations.

The results of clinical trials may be unfavorable or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant clearance of a product. The commencement or completion of any clinical trial may be delayed or halted or may be deemed 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 any activity defined as “manufacturing”;
- the Quality Management System Regulation (“QMSR”), which imposes requirements for risk management, design/document controls, purchasing, traceability, and production/process controls on manufacturers, including third-party manufacturers;
- labeling regulations, which (among other requirements and restrictions) prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;

- medical device reporting (“MDR”), per which manufacturers must 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;
- mandatory reporting of corrections and removals taken to reduce a risk to health or remedy a violation of the Food, Drug, and Cosmetic Act caused by the device which may present a risk to health; and
- voluntary recalls of devices.

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

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

- Warning letters or Untitled letters;
- fines, injunctions and civil penalties;
- product recall or seizure;
- civil fines and penalties;
- delays in clearing or refusal to clear products;
- import alerts or refusals;
- 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 QMSR. The QMSR (which replaces the prior Quality System Regulation (“QSR”)) requires medical device establishments to maintain 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 QMSR through periodic announced and unannounced inspections that may include the manufacturing facilities of subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers are not in compliance with applicable 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.

On August 7, 2025, the Company announced its decision to exit selected international operations in order to focus on the U.S. market—where the Company is seeing the strongest growth and clinical demand. This strategic realignment supports Nuwellis’ core business strategy: investing in the markets driving revenue growth. With expanding traction in U.S. cardiac surgery and pediatric programs, and a rising opportunity in the hospital-based outpatient space, the Company is streamlining operations to prioritize investment in markets where it can have the most immediate and long-term impact.

Human Capital Management

As of December 31, 2025, we had 38 employees, all of whom are full-time. We employ physicians, professionals in research and development, clinical, regulatory, manufacturing, commercial, finance, legal and other functions that are important to our business. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

Attracting, developing, and retaining highly qualified individuals are key to our success. To do so, we believe we offer competitive compensation packages-inclusive of base salary, bonus, and equity, and benefits. We also sought to establish a values-based culture enhanced by principles that set us apart: our empathy for patients and other stakeholders, our owner’s mindset, our prioritization of clarity, our cross-functional collaboration, and our sense of urgency. These values enhance the working environment for our current employees and attract our desired candidates.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained. Please See Note 4 – Subsequent Events to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Company History

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

Corporate Information

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

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

We are a “smaller reporting company” under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. As long as we remain a smaller reporting company and non-accelerated filer, we are exempt from the attestation requirement in the assessment of our internal control over financial reporting by our independent auditors pursuant to section 404(b) of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) but are required to make our own internal assessment of the effectiveness of our internal controls over financial reporting.

Item 1A. Risk Factors.

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

Risks Related to Our Business

We will need to raise additional capital to fund our operations through the end of fiscal year 2026. If additional capital is not available, we will have to delay, reduce, or cease operations.

We believe that we have sufficient capital to fund our operations through the end of the second quarter of 2026. We will need to raise additional capital to fund our operations through the end of fiscal year 2026. 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 healthcare 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 healthcare 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 healthcare 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 do so. In addition, market acceptance of the Aquadex System may require that we make enhancements to the system or its components. We cannot be sure that we will be able to successfully develop such enhancements, or that if developed they will be viewed favorably by the market. Our ability to achieve acceptance of our Aquadex System depends on our ability to demonstrate the safety, efficacy, ease-of-use and cost-effectiveness of the system. We may not be able to expand the adoption and market acceptance of the Aquadex System to both the inpatient and outpatient markets and our potential sales could be harmed.

We 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 utilization 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 salesforce 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 \$17.5 million as of December 31, 2025. As of December 31, 2025, our accumulated deficit was \$316.3 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 have identified two material weaknesses in connection with our internal control over financial reporting which, if not remediated, could adversely affect our business, reputation and stock price.

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

Our management’s evaluation of the effectiveness of our internal controls over financial reporting as of December 31, 2025, concluded that our controls were not effective, due to material weaknesses resulting from insufficient headcount to fully ensure adequate segregation of duties relating to the accounting and financial reporting function and the information technology function. Additionally, the Company did not prepare and retain contemporaneous documentation to evidence the implementation and operation of controls, including controls related to the review of balance sheet reconciliations, the preparation and recording of journal entries and controls over user access. A material weakness is a deficiency or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company’s interim or annual condensed consolidated financial statements will not be prevented or detected on a timely basis.

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

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 49.3% and 49.4% of our revenues in the twelve months ended December 31, 2025, and 2024, respectively, with our largest customer representing 13.7% and 14.4%, respectively, of our revenues during such periods. Customer ordering patterns may vary significantly from quarter.

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 because we depend on third parties for manufacturing.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for our products. We currently rely, and expect to continue to rely, on third-party contract manufacturers to manufacture our products for our commercial use. We currently work exclusively with KDI Precision Manufacturing as the sole manufacturer for the production of the Aquadex SmartFlow® Console, AquaFlexFlow® Blood Circuits, and dELC® Catheters. If any issues arise in the manufacturing and we are unable to arrange for alternative third-party manufacturing sources, we are unable to find an alternative third party capable of reproducing the existing manufacturing method or we are unable to do so on commercially reasonable terms or in a timely manner, we may not be able to meet customer demand.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our products, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreement by the third party, based on our own business priorities, at a time that is costly or damaging to us;
- current manufacturer and any future manufacturers may not be able to manufacture our products at a cost or in quantities or in a timely manner necessary to make commercially successful products;
- equipment malfunctions, power outages or other general disruptions experienced by our third-party manufacturers to their respective operations and other general problems with a multi-step manufacturing process; and

- the possible misappropriation or disclosure by the third party or others of our proprietary information, including our trade secrets and know-how.

If third-party manufacturers do not successfully carry out their contractual obligations or meet expected timelines our results of operations could be impacted. Our manufacturers are also subject to federal, state and local laws and regulations in the United States and abroad governing laboratory procedures and the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental, health and safety laws and regulations are expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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

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

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, many 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 healthcare companies, pharmaceutical companies and gene- and cell-based therapies is intense and expected to increase. The vast majority of patients with fluid overload receive pharmacological treatment (diuretics) as 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 and since the COVID-19 pandemic.

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

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.

Healthcare 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. In that regard, the Trump administration's legislative and regulatory agendas, as they relate to the healthcare and medical device industries, remain uncertain. 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 healthcare by challenging the prices charged, or deny coverage, for healthcare products and services. Any future laws, regulations, interpretations, applications or enforcement could delay or prevent regulatory approval or clearance of our Aquadex System and our ability to market our Aquadex System. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA and/or other agencies as described above, all of which could impair our ability to manufacture 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 healthcare 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 healthcare programs, private health insurance companies and managed care organizations, then reimburse our customers based on established payment formulas that consider part or all of the cost associated with these devices and the related procedures performed. Legislative proposals can substantially change the way healthcare is financed by both governmental and private insurers and may negatively impact payment rates for our system.

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

We have experienced and may continue to experience product defects or issues with quality management, which may result in lawsuits for product liability, and 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.

On December 11, 2024, we sent a notice to affected customers that we were voluntarily recalling specific lots of the AquaFlexFlow UF 500 Plus extracorporeal blood circuit which is used with the Aquadex Smartflow® or Aquadex FlexFlow® System. The lots were recalled due to failures of the blood circuit associated with too many mismatch alarms. The blood circuits may indicate "Ultrafiltrate Weight Mismatch" or "Excessive Weight Mismatch" alarms while in use. If not addressed, this failure could result in excess fluid removal from a patient leading to Acute Volume Depletion. We were made aware of five reported incidences of blood circuit product failures, with three leading to patient dehydration and requiring administration of fluids. The recall was conducted with the knowledge of the U.S. FDA which has classified the recall as Class 1.

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 have historically marketed 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.

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

On August 7, 2025, the Company announced its decision to exit selected international operations in order to focus on the U.S. market—where the Company is seeing the strongest growth and clinical demand. This strategic realignment supports Nuwellis' core business strategy: investing in the markets driving revenue growth. With expanding traction in U.S. cardiac surgery and pediatric programs, and a rising opportunity in the hospital-based outpatient space, the Company is streamlining to prioritize investment in markets where it can have the most immediate and long-term impact.

If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by 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 FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The FDA 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. The FDA also imposes requirements through the Quality Management System Regulation (“QMSR”), which include requirements for good manufacturing practices, or GMP. Failure to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States.

Our manufacturing facilities have not been inspected and certified by a Notified Body. We cannot be sure that our facilities or the processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent obtaining the approvals we need to market our products in the European Union Community and the United States.

To market our products in the 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: Warning or Untitled letters, 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.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA’s medical device reporting regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that our product(s) may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. Manufacturers are also expected to maintain certain policies, procedures, and records regarding complaints and medical device reporting. If we fail to comply with our reporting and recordkeeping obligations, the FDA could take action, including Warning letters, Untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products. In addition, information contained in an MDR could trigger FDA regulatory actions such as inspections, recalls and patient/physician notifications; and because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions.

The FDA has the authority to require the recall of a device in the event of material deficiencies or defects in design or manufacture or if it poses an unacceptable risk to health. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may, in the future, initiate voluntary withdrawals or corrections for our products that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of time and capital, will distract management from operating our business and may harm our reputation and financial results.

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 and changes to healthcare regulations.

Since its implementation beginning in 2010, the Affordable Care Act has significantly changed, and continues to change, how health care services are covered, delivered and financed in the United States. 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 future of the Affordable Care Act and its implementation, however, is uncertain as the Affordable Care Act has continuously been the subject of legal and political challenges and national debate, which itself constitutes a risk. To date, the Affordable Care Act has survived three major Supreme Court challenges and no bills wholly repealing the Affordable Care Act have passed both chambers of Congress.

Whether or not the Affordable Care Act remains in effect, it is expected that federal and state governments will continue to consider various reform proposals in the health care industry that may be adopted in the future. These reforms could have a material adverse effect on our industry generally and on our customers. We cannot predict what health care programs and regulations will be ultimately implemented at the federal or state level, particularly given the recent change in administration, or the effect of any future legislation or regulation. However, 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 change 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.

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.

Moreover, the federal 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 federal physician self-referral law, 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”) 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 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. present 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 future losses.

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

As a result of a potential acquisition, we may be required to capitalize a significant amount of intangibles, including goodwill. We would be required to 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.

Our business could be adversely affected due to risks related to proposed acquisitions and the subsequent integration of such accumulations.

On January 29, 2026, we entered into a Securities Purchase Agreement to acquire all of the issued and outstanding ordinary shares of Rendiatech Ltd., an Israeli-based medical technology company focused on automated kidney function monitoring. The transaction is expected to close following the satisfaction of customary closing conditions. We cannot be certain that we will be able to identify, consummate and successfully integrate this or any future acquisitions, and no assurance can be given with respect to the timing, likelihood or business effect of any possible transaction. Transactions that we consummate would involve risks and uncertainties to us, including mispricing the inherent value of the acquired entity, as well as potential difficulties in integrating systems, related assets, and realizing synergies.

The risks associated with our proposed acquisitions any future acquisitions include, but are not limited to:

- we could be subject to liabilities that could be material or become subject to litigation or regulatory risks as a result of the acquisition;
- unanticipated costs, delays or other operational or financial problems related to integrating the products, product candidates, technologies, business operations, systems, controls and personnel of an acquired company or asset with our company;
- failure to successfully develop and commercialize acquired products, product candidates or technologies or to achieve other strategic objectives;
- disruption of our ongoing business and diversion of our management’s and employees’ attention from ongoing development of our existing business and other opportunities and challenges; and
- unanticipated restructuring and other integration costs may be incurred.

Any of these risks, whether with respect to the proposed or any future acquisitions, could have a material adverse effect on our business and results of operations.

If we fail to comply with federal and state laws regarding off-label use of our products, we could be subject to regulatory or enforcement actions and face substantial civil and criminal penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

Our educational and promotional activities and training methods must comply with the FDCA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as “off-label” use. Health care professionals may use authorized medical devices off-label in their professional medical judgment in the care of a patient, as the FDA does not regulate the practice of medicine. Medical device companies, however, are prohibited from marketing and promoting products for indications and uses that are not authorized by FDA.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in certain types of truthful, non-misleading, and non-promotional speech concerning their products. Accordingly, we engage in medical education activities and communicate with healthcare professionals about many aspects of our products and clinical trials. In addition, we are aware that the Aquadex System, which is cleared by FDA solely for use in adults and pediatric patients weighing 20 kg or more, is being used off-label to treat patients who weigh under 20 kg, including being modified by children’s hospitals so that it can provide dialysis to neonates and other premature infants who were born either without kidneys or without normal kidney function. These patients typically have very few other treatment options given the large extracorporeal blood volume required by standard dialysis machines, the need for blood priming of the dialysis circuit and the use of large catheters.

Although we believe that all of our communications regarding off-label uses are in compliance with the relevant regulatory expectations, the FDA or another regulatory authority may disagree, and characterize such communications as marketing and promotion of an off-label use.

If the FDA determines that our, or our commercial partners' educational activities, training, and/or marketing constitutes promotion of an off-label use, it could request that we or our commercial partners cease to use, or modify, those promotional materials. We also could be subject to regulatory or enforcement actions, including the issuance of Untitled or Warning letters, injunctions, seizures, civil fines and criminal penalties, any of which could have an adverse impact on our reputation and financial results.

In addition to FDA, we may be subject to significant enforcement actions from other federal and state enforcement authorities, such as the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services ("HHS OIG"), if they consider our communications, including promotional and training materials, to constitute promotion of an uncleared, uncertified or unapproved use of a medical device. In the U.S., engaging in off-label promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These laws include the federal False Claims Act, which allows any individual to bring a lawsuit against a company on behalf of the federal government alleging submission of or causing others to submit false or fraudulent claims for payment by a federal program such as Medicare or Medicaid. Many False Claims Act lawsuits against, and preceding investigations of, manufacturers of healthcare products are brought every year, leading to several substantial civil and criminal settlements related to off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our collaborators do not lawfully promote our approved products, we may become subject to such investigations and litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, we must have adequate substantiation for the claims we make for our products and services. If any of our claims are determined to be false, misleading or deceptive, our products and services could be considered misbranded under the Federal Food, Drug, and Cosmetic Act ("FDCA") or in violation of the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act alleging that our marketing materials are false or misleading.

Foreign jurisdictions have their own laws and regulations concerning medical devices, including marketing authorizations and certifications, communications about off-label uses, and substantiation of advertising and promotional claims. Failure to comply with those laws and regulations could result in actions against us, including fines, penalties and exclusion from the market. Any such actions could adversely affect our ability to market new products and services or continue to market existing products and services in those jurisdictions.

Risks Related to Our Intellectual Property

If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.

We are subject to federal, state, and foreign healthcare laws and regulations pertaining to fraud and abuse and patients' rights. These laws and regulations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- federal civil and criminal false claims laws, including the FCA and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- the federal Health Insurance Portability and Accountability Act ("HIPAA"), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, health care benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes requirements relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS, information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis; and
- state and foreign laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors; requirements for mandatory corporate regulatory compliance programs; laws relating to patient data privacy and security; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other health care providers; and state and local laws requiring the registration of device sales and medical representatives. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different and difficult compliance and reporting requirements, increases the possibility that we may run afoul of one or more laws. The costs to comply with these regulatory requirements are becoming more expensive and will also impact our profitability.

Because of the breadth of these laws and regulations and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our operations, including our arrangements with physicians and customers could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any such healthcare laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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

We have filed nine (9) patent applications related to our dedicated pediatric device in development. These resulted in eight (8) issued patents, one abandoned application, and one pending patent applications. The first issued patent involves a mechanical design for the therapy bags to allow easy load/unload by the user. The second issued patent involves transport mode operation on battery power, enabling patient mobility. Other pending patent applications involve an extracorporeal blood filtration machine that includes flexible source line connection, open versus closed loop fluid collection controls, a self-emptying bag, improved density measurement techniques, an algorithm to ensure reliable auto clamp safety engagement, a blood leak detector that can detect hemolyzed blood, and mechanical cartridge design to ease manufacturing assembly and user setup.

In addition, 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 patents.

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 cyberattacks and other unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws and regulations that protect the privacy of personal information and regulatory penalties. To the extent that we may engage in activities regulated by the Health Insurance Portability and Accountability Act and the Health Information Technology for Clinical and Economic Health Act we may have additional regulatory and reporting obligations. 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, 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.

Changes in U.S. federal government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, the ability to hire and retain key personnel, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Any future government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform its respective roles and may have a related impact on academic institutions and research laboratories whose funding is fully or partially dependent on both the level and the timing of funding from government sources. Robert F. Kennedy Jr., the current Secretary of the U.S. Department of Health and Human Services, which oversees the FDA has previously stated his intent to downsize or restructure this agency. We cannot anticipate the effect that any such restructuring or new appointments may have on our business.

In the event of a partial or complete government shutdown, the FDA and certain other science agencies may temporarily cease certain operations. Furthermore, during such shutdown, the FDA may maintain only operations deemed to be essential for public health while suspending the acceptance of new medical product applications and routine regulatory and compliance work related to medical products and foods.

The U.S. government has previously shut down, including for a prolonged period during the second half of 2025. Disruptions at the FDA and other agencies, such as those resulting from a restructuring of these agencies, a government shutdown, or uncertainty from stopgap spending bills may slow the time necessary for new drugs and devices to be reviewed and/or approved by necessary government agencies and may affect the ability of the healthcare and drug industries to deliver new products to the market in a timely manner, which would adversely affect our operating results and business. Interruptions to the function of the FDA and other government agencies could adversely affect the demand for laboratory space and significantly impact our operating results and our business.

If we experience an interruption in supply from a material sole-source supplier, our business may be harmed.

We are dependent on sole-source suppliers to produce raw materials including our one fully validated third-party sterilizer. If there is any interruption in supply of our raw materials from these sole-source suppliers, for any reason, there can be no assurance that we will be able to obtain adequate alternative quantities of the raw materials within a reasonable time or at commercially reasonable prices. Our suppliers could discontinue the manufacturing or supply of these components at any time.

We do not carry a significant inventory of some of these components. Our suppliers may not be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those suppliers or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us. In addition, if these suppliers are unable to deliver components to us, whether due to a labor shortage, slow down or stoppage, or for any other reason, we would be required to seek alternative suppliers. We might not be able to identify and qualify additional or replacement suppliers for any of these components quickly or at all or without incurring significant additional costs.

We cannot guarantee that we will be able to establish and validate alternative relationships on similar terms, without delay or at all. Finding and validating alternative suppliers may not be feasible or could take a significant amount of time and involve significant expense, and any such delay could significantly harm our business resulting in backorders, production delays and rationing end-user product availability. While we have taken steps to attempt to mitigate the impact of potential supply shortages, a future shortage may have a negative impact on our ability to manufacture our products and harm our business.

Risks Related to Our Common Stock

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

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, both of which are requirements where we have been deficient in recent years. 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.

On June 10, 2025, the Company closed an offering of 61,444 shares of its common stock and pre-funded warrants to purchase 335,381 shares of common stock, in each case with accompanying Series A Warrants to purchase up to 1,190,480 shares of common stock (“Series A Warrants”) and Series B Warrants to purchase up to 396,829 shares of common stock (“Series B Warrants”, collectively, the “June 2025 Offering”. The public offering price per share of common stock and accompanying warrants is \$12.60 per share and accompanying warrants, and the public offering price per pre-funded warrant and accompanying warrants is \$12.5958 per pre-funded warrant and accompanying warrants. The Series B Warrants had an exercise price of \$12.60 and are exercisable for a period of five years following the receipt of stockholder approval, which we obtained on August 4, 2025. The Series A Warrants contained a one-time reset of the exercise price in the event that the Company implemented the 2025 Reverse Stock Split (as defined below) equal to the greater of: (i) 20% of the combined public offering price per share of common stock and accompanying warrants in the offering and (ii) the lowest daily volume-weighted-average price for the five trading days immediately following the date of the implementation of the 2025 Reverse Stock Split.

As a result of specific terms included in the Series A Warrants and the Series B Warrants, it was determined that outstanding Series A Warrants and the Series B Warrants should be classified as a liability on the Company’s balance sheet until (i) in the case of the Series A Warrants, the price reset is triggered in connection with the reverse split or (ii) the warrants are exercised for shares of common stock.

On July 3, 2025, the Company consummated a one-for-forty-two reverse stock split of the Company's issued and outstanding shares of common stock (the "2025 Reverse Split"). As a result of this reverse stock split, the price reset provision of the Series A Warrants was triggered, resulting in the exercise price being reduced to \$7.00 per share, and the transition of any outstanding Series A Warrants from being classified as a liability on the Company's balance sheet into equity. On August 4, 2025 at a special meeting our stockholders approved, among other things, the exercise of the Series A and Series B Warrants in accordance with Nasdaq Listing Rule 5635(d). Following this special meeting, the holders of the Series B Warrants exercised a majority of the outstanding warrants, resulting in the removal of a majority of the liability associated with the outstanding Series B Warrants from the Company's balance sheet.

As a result of the above, the Company's stockholders' equity as of June 30, 2025, as reported in the interim financial statements included in the Company's Quarterly Report on Form 10-Q, was below the amount required to be in compliance with the minimum stockholders' equity requirement for continued listing on Nasdaq, under Listing Rule 5550(b)(1) (the "Stockholder's Equity Requirement"). However, as of the date of the filing of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, the liability associated with the Series A Warrants was reclassified as equity and a majority of the liability associated with the Series B Warrants was removed, resulting in a pro forma stockholders' equity of \$4,507 (in thousands) as of June 30, 2025, and therefore the Company believes it continues to be compliance with the minimum Stockholders' Equity Requirement.

On June 18, 2025, the Company received a Deficiency Notice from the Listing Qualifications Department of Nasdaq informing the Company that because the closing bid price for the Company's common stock listed on Nasdaq was below \$1.00 for 30 consecutive trading days, the Company was not in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Deficiency Notice also indicated that the Company was not eligible for any compliance period specified in Nasdaq Listing Rule 5810(c)(3)(A) because the Company effected a reverse stock split over the prior one-year period or has effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one; accordingly, the Company was informed that its securities were subject to delisting from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). As previously disclosed, the Company effected the 2024 Reverse Stock Split on June 27, 2024. The Company timely requested a hearing before the Panel, which was scheduled for August 12, 2025. At its annual meeting held on May 20, 2025, the Company's stockholders approved a proposal allowing the board of directors of the Company to effect a reverse split in the range of 1-for-5 to 1-for-70. The Company's board of directors authorized the 2025 Reverse Stock Split to regain compliance with the Minimum Bid Price Requirement. On July 22, 2025, the Company received formal notice from Nasdaq stating that it has resolved the previously disclosed bid price deficiency. As a result, the hearing previously scheduled with the Nasdaq Hearings Panel for August 12, 2025 was cancelled, and shares of the Company's Common Stock continue to be listed and traded on the Nasdaq Capital Market under the ticker "NUWE."

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

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

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

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.

Nasdaq has proposed enhanced listing standards, which could adversely affect our ability to maintain our Nasdaq listing and access to capital markets.

Our common stock is listed for trading on Nasdaq. We must satisfy Nasdaq’s continued listing requirements, including, among other things, a minimum closing bid price requirement of \$1.00 per share for thirty consecutive business days. On January 13, 2026, Nasdaq filed a rule proposal with the SEC to adopt a new continued listing requirement that would require all companies listed on Nasdaq to maintain a minimum market value of listed securities of \$5 million. Under the proposed rule, if a company’s market value of listed securities falls below this threshold for 30 consecutive trading days, Nasdaq may immediately suspend trading and initiate delisting proceedings without affording the company a compliance cure period. This proposed rule, if adopted, would be in addition to Nasdaq’s existing continued listing requirements. If the proposed rule is adopted and the market value of our common stock were to fall below the proposed \$5 million threshold or we otherwise fail to satisfy Nasdaq’s continued listing standards, we could face delisting proceedings on an accelerated basis. The delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities. The comment period for the proposed rule closed on February 19, 2026. The effective date of the proposed rule is not known, if approved and adopted.

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

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

As of December 31, 2025, we had warrants to purchase 1,334,937 shares of common stock outstanding, with exercise prices ranging from \$7.00 to \$36,750 with a weighted-average exercise price of \$16.08.

As of December 31, 2025, there were 27 shares of Series F Convertible Redeemable Preferred Stock, par value \$0.0001 per share (the “Series F Convertible Preferred Stock”) outstanding, convertible into 10,719 shares of common stock. 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 \$7,000,000). Effective for every stock offering or reverse stock split, when applicable, the conversion price of the Series F convertible preferred stock has been recalculated based on the offering price. As of July 7, 2025 (the effective date of the most recent reverse stock split), the conversion price of the Series F convertible preferred stock was recalculated to \$397.00.

On June 6, 2025, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series F-1 Convertible Preferred Stock with the State of Delaware. At that time, 100 shares of Series F Preferred Stock were outstanding and owned by the Company's Chief Executive Officer, John L. Erb. Such 100 shares of Series F Preferred Stock were exchanged for Series F-1 Preferred Shares pursuant to a Securities Exchange Agreement between John L. Erb and the Company, dated June 9, 2025. On June 9, 2025, 66 shares of the Series F-1 Preferred shares were converted into 26,191 shares of the Company's Common Stock. The conversion rate for the 66 Series F-1 Preferred Shares was \$397.00 per share. As of December 31, 2025, 66 of the series F-1 Preferred shares had been converted to Common Stock and 34 shares remained outstanding, convertible into 13,498 shares of common stock.

As of December 31, 2025, there were 137 shares of Series J Convertible Preferred Stock (as defined below) outstanding, convertible into 81 shares of common stock and 582 Series J Convertible Preferred Stock issuable upon the exercise of 47 warrants issued in the October 2023 Offering (as defined below).

If any security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock could depress the trading market for our common stock over an extended period of time. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, 2025, we have outstanding warrants to purchase an aggregate of approximately 1,334,937 shares of our common stock, and options to purchase an aggregate of approximately 4,452 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 27 shares of Series F Convertible Preferred Stock outstanding, 34 shares of Series F-1 Convertible Preferred Stock outstanding and 137 shares of Series J Convertible Preferred Stock outstanding as of December 31, 2025. Upon liquidation, dissolution or winding-up of the Company, holders of our Series F Convertible Preferred Stock and Series J Convertible Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of such preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, *pari passu* with all the holders of common stock.

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

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

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

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

On July 3, 2025, we effected a 1-for-42 reverse split of our outstanding common stock. This reverse stock split did not change the par value of our common stock or the number of common or preferred shares authorized by our Fourth Amended and Restated Certificate of Incorporation, as amended (our “Certificate of Incorporation”). Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors’ ability to issue authorized and unissued shares without further stockholder action. As of December 31, 2025 our Certificate of Incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F and Series F-1 Convertible Preferred Stock, 600,000 of which are designated Series J Convertible Redeemable Preferred Stock and we have 1,685,817 shares of common stock outstanding, 1,334,937 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, 582 Series J Convertible Preferred Stock issuable upon the exercise of 47 warrants issued in the October 2023 Offering, and 35,124 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.

Some companies that have experienced volatility in the market price of their stock, have been subject to securities class action litigation and we may continue to be a target in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could materially adversely affect our business, results of operations, and financial condition.

Our stock could be the target of short sellers who may seek to drive down the price of shares by disseminating negative reports or information about us. Such negative publicity may lead to additional public scrutiny or may cause further volatility in our stock price, a decline in the value of a stockholder's investment in us or reputational harm. Volatility in our stock price also impacts the value of our equity compensation, which affects our ability to recruit and retain employees. Accordingly, substantial or sustained stock price declines could have a material adverse impact on stockholder confidence and employee recruiting and retention.

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 healthcare 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.

We are subject to litigation which could result in a material impact on our business, results of operations, and financial condition.

Following our announcement of our private placement on January 29, 2026, E.F. Hutton & Co. ("*Hutton*") filed a complaint against the Company with the Supreme Court of the State of New York. The complaint alleges, among other things, that we breached our engagement letter with Hutton to act as its exclusive placement agent for our future financings, as discussed in more detail in Part I, Item 3. "Legal Proceedings". This lawsuit and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend and resolve, and will divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and other suits, and we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price.

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

As of December 31, 2025, we had U.S. net operating loss (“NOL”) carryforwards of approximately \$240.4 million for U.S. federal income tax purposes. Approximately \$118.9 million of NOL carryforwards will expire from 2026 through 2038. Pursuant to the Tax Cuts and Jobs Act of 2017, the NOL carryforwards generated in 2018 through 2025 totaling approximately \$121.5 million do not expire. The expiration of state NOL carryforwards will vary by jurisdiction. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code. The Company does not have any foreign tax loss carryovers.

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

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

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

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

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

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

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

We are a “smaller reporting company” under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

Worldwide economic and market conditions, an unstable economy and other adverse developments, including inflation, could adversely affect our business, results of operations and liquidity, and stock price.

As widely reported, in recent years, global credit and financial markets have experienced volatility and disruptions, including declines in consumer confidence, concerns about declines in economic growth and unemployment, increases in the rate of inflation, increases in borrowing rates and changes in liquidity and credit availability, and uncertainty about geopolitical events and other challenges affecting the global economy, including most recently in connection with actions undertaken by the U.S. Federal Reserve Board to address inflation, the Ukraine-Russia and Israel-Hamas conflicts and supply chain disruptions. These factors could lead to further disruption, instability, and volatility in global markets, continue to increase inflation, disrupt supply chains, adversely affect consumer confidence and disposable income levels and have other impacts on our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn. These factors could have a negative impact on our potential sales and operating results.

Changes in spending or budgetary priorities may materially adversely affect our business.

Our business is dependent upon the FDA and the FDA’s ability to timely respond to our product development activities. On January 20, 2025, President Trump signed an executive order creating an advisory commission, the “Department of Government Efficiency” to reform federal government processes and reduce expenditures. Pressures on and uncertainty surrounding the U.S. federal government’s budget, and potential changes in budgetary priorities and spending levels, could adversely affect staffing levels and the funding for the FDA. Disruptions in how the FDA operates due to these policies may materially adversely affect our business.

Changes to U.S. tariff and import/export regulations may have a negative effect on our suppliers and/or service providers and, in turn, could have a material adverse impact on our financial condition.

The United States has recently enacted and proposed to enact significant new tariffs. Additionally, President Trump has directed various federal agencies to further evaluate key aspects of U.S. trade policy and there have been ongoing discussion and commentary regarding potential significant changes to U.S. trade policies, treaties and tariffs. On February 20, 2026, the Supreme Court struck down the bulk of President Trump’s sweeping tariffs, ruling that the administration overstepped its authority by using the International Emergency Economic Powers Act (IEEPA) to impose them. Hours after the ruling, President Trump signed an executive order for a new 10% global import duty using Section 122 of the Trade Act of 1974. These actions have caused substantial uncertainty and volatility in financial markets and may result in retaliatory measures on U.S. goods.

There continues to exist significant uncertainty about the future relationship between the United States and other countries with respect to such trade policies, treaties and tariffs. These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly impact the cost of Aquadex System, and other parts and supplies sourced internationally or impact the cost of service providers located outside of the United States, which in turn would negatively impact us.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

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

We have a cross-departmental approach to addressing cybersecurity risk, including input from our board of directors. The board of directors, Audit Committee, and senior management devote what we believe are appropriate resources to cybersecurity and risk management processes to adapt to the changing cybersecurity landscape and respond to emerging threats in a timely and effective manner. Our cybersecurity risk management protocols are comprised of software programs including antivirus protection, end-point threat detection, remote access controls, and multifactor authentication. In addition, we have a set of Company-wide policies and procedures concerning cybersecurity matters, which include an employee handbook as well as other policies that directly or indirectly relate to cybersecurity, such as policies related to incident response, confidential information and the use of internet, social media, email and wireless devices.

Our Director of Operations is responsible for developing and implementing our information security program and reporting on cybersecurity matters to the board of directors. Nuwellis leverages third-party IT service provider and specifically their cybersecurity expertise.

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

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

The Audit Committee and the full board of directors periodically participate in discussions with management and among themselves regarding cybersecurity risks. As of 2024 the Audit Committee performs an annual review of the Company's cybersecurity program, which includes discussion of management's actions to identify and detect threats, as well as planned actions in the event of a response or recovery situation. The Audit Committee's annual review also includes review of recent enhancements to the Company's defenses and management's progress on its cybersecurity strategic roadmap.

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

We face a number of cybersecurity risks in connection with our business. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we have, from time to time, experienced threats to and breaches of our data and systems, including malware and computer virus attacks. Such occurrences could negatively impact our business strategy, reputation and results of operations.

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 \$36,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease.

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

Item 3. Legal Proceedings.

On February 11, 2026, E.F. Hutton & Co. (“**Hutton**”) filed a complaint against the Company with the Supreme Court of the State of New York. The complaint alleges, among other things, that the Company breached its engagement letter with Hutton to act as its exclusive placement agent for the Company’s registered securities offerings. The complaint seeks compensatory damages, punitive damages, interest, costs and attorneys’ fees. The Company intends to vigorously defend itself in this matter; however, in light of, among other things, the preliminary stage of the litigation, the Company is unable to provide any assurances as to the ultimate outcome of the lawsuit and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome. The Company has not yet filed an answer to the complaint. Please See Note 4 – Subsequent Events to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information. Commencing February 16, 2012, our shares of common stock began trading on the Nasdaq Capital Market, where it now trades under the symbol “NUWE.” Prior to that, there was no public trading market for our common stock.

Stockholders of Record. As of March 6, 2026, we had 2,310,477 shares of common stock issued and outstanding, and one holder of record of our common stock. A substantially greater number of stockholders may be “street name” or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

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

Recent Sales of Unregistered Securities. On June 6, 2025, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series F-1 Convertible Preferred Stock (the “F-1 Certificate of Designation”) with the Secretary of State of the State of Delaware, authorizing the issuance of 100 shares of Series F-1 Convertible Preferred Stock (the “Series F-1 Preferred Stock”). The terms of the Series F-1 Preferred Stock are substantially similar to the terms of the Company’s existing Series F Convertible Preferred Stock (the “Existing Series F Stock”), that were issued pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock that was filed with the Secretary of State of the State of Delaware on November 22, 2017, except that the F-1 Certificate of Designation provides that the Company shall not affect any conversion of the shares of Series F-1 Preferred Stock to the extent that, after giving effect to an attempted conversion, the holder of shares of Series F-1 Preferred Stock (together with such holder’s affiliates and any persons acting as a group together with such holder or any of such holder’s affiliates) would beneficially own a number of shares of common stock in excess of 19.99% of the shares of common stock then outstanding. On June 9, 2025, pursuant to Section 3(a)(9) of the Securities Act of 1933, as amended, the Company entered into a Securities Exchange Agreement (the “Exchange Agreement”) with John L. Erb, the Company’s Chief Executive Officer and member of the board of directors, pursuant to which the Company agreed to issue 100 shares of the Company’s newly designated Series F-1 Stock in exchange for 100 shares of the Company’s outstanding Existing Series F Stock (the “Exchange”). Following the Exchange, Mr. Erb will own 100% of the Series F-1 Stock.

There were no other unregistered sales of equity securities during the year ended December 31, 2025 that were not reported on a Current Report on Form 8-K.

Item 6. [Reserved].

Item 7. Management’s Discussion and Analysis of Financial Conditions 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

Nuwellis is dedicated to advancing cardiorenal care by enabling earlier, safer, and more controlled fluid management for patients. 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 eight 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.

Recent Developments

Nasdaq Compliance

On June 18, 2025, Nuwellis, Inc. (the “Company”) received a letter (the “Deficiency Notice”) from the Listing Qualifications Department (the “Staff”) of the Nasdaq Stock Market (“Nasdaq”) informing the Company that because the closing bid price for the Company’s Common Stock listed on Nasdaq was below \$1.00 for 30 consecutive trading days, the Company was not in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). The Deficiency Notice also indicated that the Company was not eligible for any compliance period specified in Nasdaq Listing Rule 5810(c)(3)(A) because the Company effected a reverse stock split over the prior one-year period or has effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one; accordingly, the Company was informed that its securities were subject to delisting from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the “Panel”). As previously disclosed, the Company effected the 2024 Reverse Stock Split on June 27, 2024. The Company timely requested a hearing before the Panel, which was scheduled for August 12, 2025. At its annual meeting held on May 20, 2025, the Company’s stockholders approved a proposal allowing the board of directors of the Company to effect a reverse split in the range of 1-for-5 to 1-for-70. The Company’s board of directors authorized the 2025 Reverse Stock Split to regain compliance with the Minimum Bid Price Requirement. On July 22, 2025, the Company received formal notice from Nasdaq stating that it had resolved the previously disclosed bid price deficiency. As a result, the hearing previously scheduled with the Nasdaq Hearings Panel for August 12, 2025, was cancelled, and shares of the Company’s Common Stock continue to be listed and traded on the Nasdaq Capital Market under the ticker “NUWE.”

Public Offerings

On June 10, 2025, the Company announced the closing of its public offering of 61,444 shares of its Common Stock, pre-funded warrants to purchase 335,381 shares of Common Stock (all pre-funded warrants were exercised on this date), in each case with accompanying Series A Warrants to purchase up to 1,190,480 shares of Common Stock, Series B Warrants to purchase up to 396,829 shares of Common Stock and Placement Warrants to purchase up to 11,903 shares of Common Stock with gross proceeds of approximately \$5.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants. The public offering price per share of Common Stock and accompanying warrants is \$12.60 per share and accompanying warrants, and the public offering price per pre-funded warrant and accompanying warrants is \$12.5958 per pre-funded warrant and accompanying warrants. Each pre-funded warrant has an exercise price of \$0.0042 per pre-funded warrant and was immediately exercisable. The Series B Warrants have an exercise price of \$12.60 and will be exercisable for a period of five years following the receipt of stockholder approval which was obtained on August 4, 2025, as required by the applicable rules and regulations of Nasdaq. The Series A Warrants contain a one-time reset of the exercise price in the event that the Company implemented the 2025 Reverse Stock Split equal to the greater of: (i) 20% of the combined public offering price per share of Common Stock and accompanying warrants in the offering and (ii) the lowest daily volume weighted average price for the five trading days immediately following the date of the implementation of the 2025 Reverse Stock Split. After the reverse stock split was effectuated on July 3, 2025, the reset exercise price of the Series A warrants was set at \$7.00 per share and there were no further contractual exercise price adjustments following the reverse split. The Series B Warrants include a zero cash exercise option allowing holders of a Series B Warrant the right to receive, without payment of any additional cash to the Company, an aggregate number of shares equal to the number of shares of Common Stock that would be issuable upon a cash exercise of such Series B Warrants.

The Series A and B warrants offered in this financing were determined to be classified as a liability on the condensed consolidated balance sheet. An independent valuation of the warrants was performed and reviewed with management. The Series A warrants were valued using the Monte Carlo Simulation Model utilizing US Treasury Rates, Volatility rates, Common Stock price and assumptions around date and likelihood of a reverse split exercise price adjustment. The Series B warrants were valued using the Common Stock price given the zero-exercise price. The valuation at issuance was \$10.6 million for the Series A warrants and \$3.9 million for the Series B warrants, and on June 30, 2025, was \$10.0 million for the Series A warrants and \$3.7 million for the Series B warrants, representing a warrant liability decrease of \$0.8 million from issuance. The \$0.8 million warrant liability decrease from issuance has been reported on the condensed consolidated statement of operations as a "Change in fair value of warrant liability." The total warrant valuation of \$14.5 million exceeded the gross proceeds of \$5.0 million. Accordingly, if the warrant valuation exceeds the gross proceeds, the difference will be recorded as "Day 1 interest." You will find this difference, along with other issuance costs (discounts, legal fees, printing) reported on the condensed consolidated statement of operations as "Financing expense."

As a result of the above, the Company's stockholders' equity as of June 30, 2025 was below the Nasdaq Stockholders' Equity Requirement. However, subsequently the liability associated with the Series A Warrants of \$8.4 million was reclassified on July 14, 2025 as equity due to the exercise price being reset to the floor at \$7.00 per share. The majority of the liability associated with the Series B Warrants has been removed as these were exercised into Common Stock. As of December 31, 2025, there were 6,268 Series B warrants still unexercised and the fair value of these warrants was \$21,004.

Private Placement

On January 29, 2026, the Company entered into a securities purchase agreement with a certain institutional accredited investor in connection with a private placement for the offer, issuance and sale of (i) 994,537 pre-funded common stock purchase warrants (the "Pre-Funded Warrants") to purchase up to 994,537 shares of the Company's common stock (the "Pre-Funded Warrant Shares"), \$0.0001 par value and (ii) 1,989,074 common warrants (the "Common Warrants"), and together with the Pre-Funded Warrants, to purchase up to 1,989,074 shares of Common Stock and together with the Pre-Funded Warrant Shares and the Pre-Funded Warrants, for a combined purchase price of \$3.09.

Under the terms of the Pre-Funded Warrants and Common Warrants, a holder will not be entitled to exercise any portion of any Pre-Funded Warrant or Common Warrant, if, upon giving effect to such exercise, the aggregate number of shares of Common Stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder's affiliates, and any other persons whose beneficial ownership of Common Stock would or could be aggregated with the holder's or any of the holder's affiliates for purposes of Section 13(d) or Section 16 of the Securities Exchange Act of 1934, as amended would exceed 4.99% (or, upon election by a holder prior to the issuance of any Pre-Funded Warrants or Common Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise as such percentage ownership is calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Securities and Exchange Commission. A holder may increase or decrease the Beneficial Ownership Limitation to a higher or lower percentage (not to exceed 9.99%), effective 61 days after written notice to the Company.

The gross proceeds from the Private Placement to the Company were approximately \$3.1 million, before deducting the placement agent's fees and related offering expenses. The Company intends to use the net proceeds from the Private Placement for working capital and general corporate purposes.

Warrant Inducement

On January 29, 2026, the Company entered into a warrant inducement offer letter with a certain investor to immediately exercise warrants issued to that investor in June 2025 and November 2024 at a reduced exercise price of \$2.84 and the Company issued to the investor a new Common Stock Purchase Warrant (the "January Inducement Warrants") to purchase up to a number of shares of common stock equal to 200% of the number of shares of Common Stock issued pursuant to the immediate exercise of the corresponding June 2025 warrants and November 2024 warrants. The January Inducement Warrants have an exercise price of \$2.84 per share, were exercisable immediately upon issuance, and expire upon the five-year anniversary of the date that a resale registration statement related to the January Inducement Warrant issued in the January Inducement Offer becomes effective.

The Company received aggregate gross proceeds of approximately \$1.9 million from the exercise of the June 2025 warrants and November 2024 warrants resulting in the issuance of up to an aggregate of 623,585 shares of Common Stock, subject to application of applicable beneficial ownership blockers. As of January 29, 2026, the Company had 1,686,892 shares of common stock issued and outstanding.

The Company also issued to the Placement Agent, or its designees, warrants to purchase up to 48,544 shares of our Common Stock as part of the compensation payable to the Placement Agent in connection with the Private Placement and January Inducement Offering. The Placement Agent Warrants have substantially the same terms as the January Inducement Warrants described above, except that the Placement Agent Warrants have an exercise price of \$5.0985 per share.

Contract with KDI

On May 12, 2025, the Company announced it had finalized an agreement with KDI Precision Manufacturing to support the next phase of Nuwellis' growth. The Company made a contractual payment of \$240,000 on July 15, 2025 to initiate the transition of the production process to KDI. This strategic relationship is expected to expand Nuwellis' manufacturing capabilities, streamline operations, and enhance the Company's ability to deliver high-quality products to healthcare providers and patients. Under the agreement, KDI will assume assembly responsibilities for the Aquadex SmartFlow® Console, AquaFlexFlow® Blood Circuits, and dELC® Catheters. To ensure a seamless transition and protect product expertise, Nuwellis assembly employees were hired by KDI. Sales, customer service, product design, and post-market surveillance will continue to reside within Nuwellis. During the third quarter of 2025, console manufacturing and calibration of consoles were moved to the KDI facility. As of December 31, 2025, all circuit and catheter manufacturing personnel had transitioned to the KDI facility and were converted to KDI employees.

Reverse Stock Split

On June 19, 2025, the Board approved the 2025 Reverse Stock Split. On July 2, 2025, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation (the "Certificate of Amendment") to effect the 2025 Reverse Stock Split, which became effective as of 5:00 p.m. Eastern Time on July 3, 2025, and the Company's Common Stock began trading on a split-adjusted basis when the market opened on July 7, 2025. When the 2025 Reverse Stock Split became effective, every forty-two shares of the Company's issued and outstanding Common Stock (and such shares held in treasury) automatically converted into one share of Common Stock, without any change in the par value per share. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the conversion of the Company's outstanding shares of preferred stock and exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of Common Stock and the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans. Any fraction of a share of Common Stock that was created as a result of the 2025 Reverse Stock Split was rounded down to the next whole share and the stockholder received cash equal to the market value of the fractional share, determined by multiplying such fraction by the closing sales price of the Company's Common Stock as reported on Nasdaq on the last trading day before the 2025 Reverse Stock Split becomes effective. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

REVERSE-HF Clinical Trial

On July 17, 2025, the Company announced the termination of its REVERSE-HF clinical trial, a randomized post-market trial evaluating ultrafiltration versus IV loop diuretic therapy for fluid management in hospitalized heart failure patients. This decision reflects the Company's strategic commitment to prioritize resources in areas demonstrating the greatest potential for patient impact and business growth—namely, outpatient heart failure, pediatric, and critical care. The Company anticipates it will save approximately \$4.0M over the next 2.5 years by terminating the REVERSE-HF clinical trial.

International Operations

On August 7, 2025, the Company announced its decision to exit selected international operations in order to focus on the U.S. market—where the Company is seeing the strongest growth and clinical demand. This strategic realignment supports Nuwellis' core business strategy: investing in the markets driving revenue growth. With expanding traction in U.S. cardiac surgery and pediatric programs, and a rising opportunity in the hospital-based outpatient space, the Company is streamlining to prioritize investment in markets where it can have the most immediate and long-term impact.

Stock Purchase Agreement

On January 29, 2026, the Company announced that it entered into a Securities Purchase Agreement to acquire all of the issued and outstanding capital stock of Rendiatech Ltd., an Israeli-based medical technology company focused on automated kidney function monitoring. The transaction is expected to close following the satisfaction of customary closing conditions.

At The Market Offering Agreement

On September 3, 2025, the Company entered into an At The Market Offering Agreement (the "Sales Agreement") with Ladenburg Thalmann & Co. Inc. ("Ladenburg") pursuant to which the Company may sell shares of the Company's Common Stock, from time to time, at its option, through or to Ladenburg, as sales agent or principal. Sales of the Company's Common Stock made pursuant to the Sales Agreement were made under the Company's Registration Statement on Form S-3 (File No. 333-280647) and the prospectus supplement filed on September 3, 2025 with the Securities and Exchange Commission, in sales deemed to be "at the market offerings" as defined in Rule 415 promulgated under the Securities Act, initially having an aggregate offering price of up to \$4,650,000. Ladenburg will use its commercially reasonable efforts to sell the Common Stock from time to time, based upon the Company's instructions (including any price, time, or size limits or other customary parameters or conditions the Company may impose). As of December 31, 2025, the Company had sold 768,535 of Common Shares for net proceeds of approximately \$3.2 million.

The Company is not obligated to make any sales of Common Stock under the Sales Agreement, and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. The offering of Common Stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. The Company is obligated to pay Ladenburg an aggregate sales agent commission of up to 3.0% of the gross proceeds of the sale price for Common Stock sold under the Sales Agreement. The Company has also provided Ladenburg with customary indemnification rights and expense reimbursements for up to \$50,000 of expenses in addition to ongoing diligence expenses. The representations, warranties and covenants contained in the Sales Agreement were made only for purposes of the Sales Agreement as of specific dates indicated therein, were solely for the benefit of Ladenburg and to allocate risk between the Company and Ladenburg, and as a result should not be relied on and may be subject to limitations agreed upon by the parties.

Robert B. Scott resigned from the Company as Chief Financial Officer effective October 24, 2025. Carisa Schultz was appointed by the Company's board of directors to serve as Chief Financial Officer, Principal Financial Officer, and Principal Accounting Officer effective February 2, 2026.

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 valuation of equity instruments, 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.

Accounting for Warrants

We have issued and may continue to issue warrants to purchase shares of common and convertible preferred stock through our public and private offerings. We account for such warrants in accordance with ASC 480 *Distinguishing Liabilities from Equity*, which identifies three categories of freestanding financial instruments that are required to be accounted for as a liability. If determined to be classified as a liability, we will initially measure the fair value of the warrants upon issuance and subsequently remeasure the fair value of the warrants at each exercise/transaction date and balance sheet date. If determined to be classified as equity, the fair value of the warrants will be measured as of the grant date and will not be subject to remeasurement at each balance sheet date.

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

Loss per Share

Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. (See Note 4 – Stockholders' Equity to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.)

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

Impairment of Long-Lived Assets

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

The Company continues to report operating losses and negative cash flows from operations, both of which it considers to be indicators of potential impairment. Therefore, the Company evaluates its long-lived assets for potential impairment at each reporting period. The Company has concluded that its cash flows from the various long-lived assets are highly interrelated and, as a result, the Company consists of a single asset group. As the Company expects to continue incurring losses in the foreseeable future, the undiscounted cash flow step was therefore bypassed, and the Company proceeded to measure fair value of the asset group. The Company had contracted with an independent fixed asset appraiser in 2024 to determine the fair value of the asset groups using a combination of the indirect cost method and income method to value the long-lived assets. The Company's fixed asset purchases for fiscal 2025 were immaterial, so the Company was able to utilize the same valuation report as was used in fiscal 2024. There have been no impairment losses recognized for the years ended December 31, 2025 or December 31, 2024.

Going Concern

Our consolidated financial statements have been prepared and presented on a basis assuming we continue as a going concern. During the years ended December 31, 2025, and 2024, 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, 2025, we had an accumulated deficit of \$316.3 million and we expect to incur losses for the foreseeable future. To date, we have been funded by equity financings, and although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably. These factors raise substantial doubt about the Company's ability to continue as a going concern through at least twelve months from the report date.

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

During 2021 and through December 31, 2025, we closed on underwritten public and other equity offerings for aggregate net proceeds of approximately \$57.0 million after deducting the underwriting discounts and commissions or placement agents' fees and offering expenses, as applicable, and other costs associated with the offerings. See Note 4 –Stockholders' Equity, to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. The Company will require additional funding to grow its business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the issuance of equity securities or other financing transactions. Should future capital raising be unsuccessful, the Company may not be able to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

We believe that our existing capital resources will be sufficient to support our operating plan through the end of the second quarter of fiscal 2026; however, there can be no assurance of this. We intend to seek to raise additional capital to support our growth or other strategic initiatives through debt, equity, or a combination thereof. There can be no assurance the Company will be successful in raising additional capital.

Internal Controls and Procedures

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

RECENT ACCOUNTING PRONOUNCEMENTS

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The guidance requires expanded interim and annual disclosures of segment information including the disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within segment profit and loss. The guidance is effective for the Company’s fiscal 2024 Form 10-K and interim periods thereafter. (see Note 11 — Segment Reporting).

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The new guidance is expected to improve income tax disclosures primarily related to the rate reconciliation and income taxes paid information by requiring 1) consistent categories and greater disaggregation of information in the rate reconciliation and 2) income taxes paid disaggregated by jurisdiction. The guidance is effective on a prospective basis, although retrospective application and early adoption is permitted. The Company has adopted ASU 2023-09 for the annual period ending December 31, 2025. See further disclosure – Note 7 Income Taxes.

In March 2024, the SEC adopted rules under SEC Release No. 33-11275, *The Enhancement and Standardization of Climate-Related Disclosures for Investors*, which requires the disclosure of material Scope 1 and Scope 2 greenhouse gas emissions and other climate-related topics in annual reports and registration statements. For non-accelerated filers and smaller reporting companies, disclosure requirements will begin phasing in for fiscal years beginning on or after January 1, 2027, subject to legal challenges and the SEC’s voluntary stay of the disclosure requirements. The Company is currently evaluating the impact these rules will have on its consolidated financial statements and related disclosures.

Information regarding new accounting pronouncements, when applicable, is included in Note 1 to the consolidated financial statements included in this Annual Report on Form 10-K. The Company has considered all recent accounting pronouncements issued and their potential effects on its consolidated financial statements. The Company’s management believes that these recent pronouncements will not have a material effect on the Company’s condensed consolidated financial statements.

FINANCIAL OVERVIEW

Nuwellis is dedicated to advancing cardiorenal care by enabling earlier, safer, and more controlled fluid management for patients. Activities since inception have consisted principally of raising capital, performing research and product development, and conducting preclinical and clinical studies. During 2016, we acquired the Aquadex Business and announced that we were halting all clinical evaluations of our prior technology, the C-Pulse System. Since then, our activities have consisted mainly of expanding our sales and marketing efforts, as well as continued development of clinical evidence and new product development efforts. As of December 31, 2025, we had an accumulated deficit of \$316.3 million, and we expect to incur losses for the foreseeable future. To date, we have been funded by public and private equity financings. Although we believe that we will be able to successfully fund our operations in the future, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Net Sales

(in thousands)

<u>Year Ended</u> <u>December 31, 2025</u>	<u>Year Ended</u> <u>December 31, 2024</u>	<u>Increase (Decrease)</u>	<u>%</u> <u>Change</u>
\$ 8,270	\$ 8,740	\$ (470)	(5.4)%

Revenue is generated mainly from the sale of consoles and disposable blood filters and catheters used in conjunction with the Aquadex System. We sell primarily in the United States to hospitals and clinics through our direct salesforce. We also sold outside of the United States to independent specialty distributors, who in turn sold to hospitals and clinics in their geographic regions. The decrease in sales in the current year period is primarily due to a 2% decrease in circuit sales, lower console average selling price, lower tech services and international, and one-time prior-year SeaStar Medical Quelimune sales.

Costs and Expenses

Our costs and expenses were as follows:

(in thousands)

	<u>Year Ended</u> <u>December 31, 2025</u>	<u>Year Ended</u> <u>December 31, 2024</u>	<u>Increase (Decrease)</u>	<u>% Change</u>
Cost of goods sold	\$ 3,146	\$ 3,064	\$ 82	2.7%
Selling, general and administrative	\$ 13,518	\$ 13,455	\$ 63	0.5%
Research and development	\$ 2,712	\$ 3,209	\$ (497)	(15.5)%

Cost of Goods Sold

The increase in costs of goods sold for the year ended December 31, 2025, compared to the year ended December 31, 2024, was primarily due to unfavorable manufacturing variances and under-absorption of fixed overhead because of lower production volumes in the first half of fiscal year 2025. In December 2024, the Company had a voluntary recall of specific lots of blood circuit units from identified accounts, and accordingly, the prior year period included a non-recurring expense of approximately \$150,000.

Selling, General and Administrative

Selling, general and administrative expenses increased slightly for the current fiscal year. This was primarily driven by the addition in headcount and compensation-related expenses and slightly higher professional service fees during fiscal year 2025.

Research and Development

The decrease in R&D expenses versus the prior year was primarily driven by reduced R&D project spend.

Income Tax Expense

<i>(in thousands)</i>	Year Ended		Increase (Decrease)	% Change
	December 31, 2025	December 31, 2024		
Income tax expense	\$ 5	\$ 5	\$ —	—%

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 issuances. On July 3, 2025, we effected a 1-for-42 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 previously authorized and unissued shares without further stockholder action. As of December 31, 2025 our Certification of Incorporation provides for 100,000,000 shares of authorized common stock and 40,000,000 shares of authorized preferred stock, 30,000 of which are designated Series A Junior Participating Preferred Stock, 18,000 of which are designated Series F Convertible Preferred Stock, 100 of which are designated Series F-1 Convertible Preferred Stock, and 600,000 of which are designated Series J Convertible Preferred Stock, and we have 1,686,217 shares of common stock outstanding, 1,364,221 shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, and 42,175 shares of common stock reserved for future grant under the Company's equity incentive plans. All common stock share amounts reflected herein have been adjusted to give effect to the July 2025 reverse stock split.

On April 30, 2024, the Company closed on a best-efforts public offering (the "April 2024 Offering") of 240,571 shares of its common stock, 80,854 shares of its common stock for pre-funded warrants and warrants to purchase up to an aggregate of 3,214,288 shares of its common stock at a combined public offering price \$8.40 per share. All pre-funded warrants were exercised on the date of the offering. Each share of common stock (or prefunded warrant in lieu thereof) was sold together with one warrant to purchase one and one half shares of common stock. The warrants had an exercise price of \$2.10 per share, were exercisable immediately upon issuance, and will expire five years following the date of issuance. Each whole common warrant entitles the holder thereof to purchase one share of common stock.

The common warrants contained a reset of the exercise price, effective upon the Warrant Stockholder Approval, to a price equal to the lesser of (i) the then exercise price, (ii) the lowest volume-weighted average price for the five trading days immediately following the date we effect a reverse stock split in the future and (iii) if we effect a reverse stock split prior to obtaining approval of the Company's stockholders (the "Warrant Stockholder Approval"), the lowest volume weighted-average price for the five trading days immediately following the date we obtain the Warrant Stockholder Approval. The Company secured the Warrant Stockholder Approval on June 6, 2024. Subsequent to June 30, 2024, the number of shares underlying the common warrants was adjusted to 2,498,331 shares and the exercise price was adjusted to \$2.49 per share. In addition, the common warrants provided for full ratchet anti-dilution adjustment to the exercise price and number of shares underlying the common warrants upon our issuance of our common stock or common stock equivalents at a price per share that is less than the exercise price of the common warrants, subject to certain exemptions. In no event would the exercise price of the common warrants with respect to either adjustment be reduced below a floor price of \$2.10.

The gross proceeds to the Company from the April 2024 Offering, before deducting the placement agent fees and other offering expenses were approximately \$2.7 million.

The warrants offered in this financing were originally classified as a liability on the balance sheet. An independent valuation of the warrants was performed and reviewed with management, and the valuation at issuance was \$7.8 million. The warrants had down-round protection and the price was reset from the June 2024 reverse stock split, which was effective July 8, 2024, and from the July 2024 and the August 2024 offerings. At the August 2024 offering, the exercise price of these warrants was adjusted to \$2.10, which represented the floor price on these warrants. As the price floor was hit, there was no further down-round protection. The warrants were re-evaluated and reclassified as equity as of September 30, 2024. During the year, there were 2,737,816 warrants exercised at a weighted average exercise price of \$2.23. The warrants are fair valued on the date of exercise and the adjustment to fair value is recorded to Additional Paid in Capital. There were 2,737,816 warrants converted to equity resulting in \$5.6 million of net proceeds to Additional Paid in Capital.

On July 25, 2024, the Company closed on an offering whereby it entered into a definitive securities purchase agreement with certain institutional investors for the purchase and sale of 469,340 shares of the Company's common stock at a price of \$4.24 per share of common stock in a registered direct offering priced at-the-market under Nasdaq rules (the "July 2024 Offering").

In addition, in a concurrent private placement, the Company issued the investors warrants to purchase up to 938,680 shares of common stock. The warrants have an exercise price of \$3.99 per share, will be exercisable immediately following the date of issuance and have a term of five years from the date of issuance. The warrants issued in this offering were determined to be equity classified.

Roth Capital Partners, LLC acted as the placement agent in the July 2024 Offering.

The gross proceeds to the Company from the registered direct offering and the concurrent private placement were approximately \$2.0 million. After deducting placement agent fees and other offering expenses payable by the Company, net proceeds were approximately \$1.5 million. The Company used the net proceeds from the offering for working capital and for general corporate purposes.

On August 23, 2024, the Company entered into a placement agency agreement with Ladenburg Thalmann & Co. Inc. (the "Placement Agent") and a securities purchase agreement with certain purchasers pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 11,508 shares of the Company's common stock, \$0.0001 par value per share, at a purchase price of \$77.49 per Share and accompanying common warrant (the "August 2024 Offering").

The shares offered in the August 2024 Offering were sold pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-280647), including a base prospectus contained therein, which was originally filed with the SEC on July 1, 2024, and was declared effective by the SEC on July 9, 2024, and a related prospectus supplement, dated August 23, 2024, related to the August 2024 Offering.

In a concurrent private placement the Company also agreed to sell and issue to the Purchasers, warrants to purchase up to 11,508 shares of the Company's common stock. The common warrants have an exercise price of \$72.24 per share, were immediately exercisable and expire on the fifth anniversary on the effective date of the registration statement to be filed for the purpose of registering the shares of the Company's common stock underlying the common warrants. The warrants issued in this offering were determined to be equity classified.

The gross proceeds from the August 2024 Offering, before deducting the Placement Agent's fees and expenses and other offering expenses payable by the Company and excluding the net proceeds, if any, from the exercise of the common warrants or August Placement Agent Warrants (as defined below), were approximately \$631,000. The August 2024 Offering closed on August 26, 2024. The Company also issued to the Placement Agent, or its designees, warrants to purchase up to 348 shares of the Company's common stock as part of the compensation payable to the Placement Agent in connection with this offering (the "August Placement Agent Warrants"). The August Placement Agent Warrants were not registered pursuant to the prospectus supplement and the accompanying prospectus. The August Placement Agent Warrants have substantially the same terms as the common warrants described above, except that the August Placement Agent Warrants have an exercise price of \$127.86 per share and will expire August 23, 2029.

On November 5, 2024, the Company announced the entry into definitive agreements for the immediate exercise of certain outstanding warrants issued by the Company in the April 2024 Offering to purchase up to an aggregate of 43,637 shares of the Company's common stock at their current exercise price of \$88.20 per share for total gross proceeds of approximately \$3.8 million, prior to deducting inducement agent fees and estimated offering expenses. In consideration for the immediate exercise of the April 2024 Offering warrants, the Company issued Series I common stock purchase warrants (the "Series I Warrants") and Series II common stock purchase warrants (the "Series II Warrants") to purchase up to an aggregate of 87,274 shares of common stock. The Series I Warrants have an exercise price of \$81.48, are exercisable six (6) months from the date of issuance and have a term of five (5) years from the date of exercisability. The Series II Warrants have an exercise price of \$81.48, are exercisable six (6) months from the date of issuance, and have a term of two (2) years from the date of exercisability. The Series I Warrants and Series II Warrants are fixed priced and do not contain any variable pricing features. The Company also issued to the Placement Agent, or its designees, warrants to purchase up to 1,312 shares of the Company's Common Stock as part of the compensation payable to the Placement Agent in connection with the warrant inducement. The Series I Warrants and Series II Warrants described above were offered in a private placement pursuant to an applicable exemption from the registration requirements under Section 4(a)(2) of the Securities Act of 1933 (the "Securities Act"), and have not been registered under the Securities Act, and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission (the "SEC") or an applicable exemption from such registration requirements. The securities were offered only to accredited investors. The Company filed a registration statement with the SEC covering the resale of the shares of common stock issuable upon exercise of the Series I Warrants, Series II Warrants, and the warrants issued to the Placement Agent in the August 2024 offering and November 2024 warrant inducement.

On June 10, 2025, the Company announced the closing of its public offering of 61,444 shares of its Common Stock, pre-funded warrants to purchase 335,381 shares of Common Stock (all pre-funded warrants were exercised on this date), in each case with accompanying Series A Warrants to purchase up to 1,190,480 shares of Common Stock and Series B Warrants to purchase up to 396,829 shares of Common Stock and Placement Warrants to purchase up to 11,903 shares of Common Stock with gross proceeds of approximately \$5.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants. The public offering price per share of Common Stock and accompanying warrants was \$12.60 per share and accompanying warrants, and the public offering price per pre-funded warrant and accompanying warrants was \$12.5958 per pre-funded warrant and accompanying warrants. Each pre-funded warrant has an exercise price of \$0.0042 per pre-funded warrant and was immediately exercisable. The Series B Warrants have an exercise price of \$12.60 and will be exercisable for a period of five years following the receipt of stockholder approval, as required by the applicable rules and regulations of Nasdaq. The Series A Warrants contain a one-time reset of the exercise price in the event that the Company implemented the 2025 Reverse Stock Split equal to the greater of: (i) 20% of the combined public offering price per share of Common Stock and accompanying warrants in the offering and (ii) the lowest daily volume-weighted-average price for the five trading days immediately following the date of the implementation of the 2025 Reverse Stock Split. After the reverse stock split effectuated on July 3, 2025, the reset exercise price of the Series A warrants was set at \$7.00 per share. The Series B Warrants include a zero cash exercise option allowing holders of a Series B Warrant the right to receive, without payment of any additional cash to the Company, an aggregate number of shares equal to the number of shares of Common Stock that would be issuable upon a cash exercise of such Series B Warrants.

On September 3, 2025, the Company entered into a Sales Agreement with Ladenburg pursuant to which the Company may sell shares of the Company's Common Stock, from time to time, at its option, through or to Ladenburg, as sales agent or principal (an "At The Market or ATM Offering."). Sales of the Company's Common Stock made pursuant to the Sales Agreement, were made under the Company's Registration Statement on Form S-3 (File No. 333-280647) and the prospectus supplement filed on September 3, 2025 with the Securities and Exchange Commission, in sales deemed to be "at the market offerings" as defined in Rule 415 promulgated under the Securities Act, initially having an aggregate offering price of up to \$4,650,000. Ladenburg will use its commercially reasonable efforts to sell the Common Stock from time to time, based upon the Company's instructions (including any price, time, or size limits or other customary parameters or conditions the Company may impose). The Company is not obligated to make any sales of Common Stock under the Sales Agreement, and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. The offering of Common Stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. The Company is obligated to pay Ladenburg an aggregate sales agent commission of up to 3.0% of the gross proceeds of the sale price for Common Stock sold under the Sales Agreement. The Company has also provided Ladenburg with customary indemnification rights and expense reimbursements for up to \$50,000 of expenses in addition to ongoing diligence expenses. The representations, warranties and covenants contained in the Sales Agreement were made only for purposes of the Sales Agreement as of specific dates indicated therein, were solely for the benefit of Ladenburg and to allocate risk between the Company and Ladenburg, and as a result should not be relied on and may be subject to limitations agreed upon by the parties. As of December 31, 2025, 768,535 shares of Common Stock had been sold with total net proceeds of approximately \$2.9 million pursuant to the terms of the Sales Agreement.

On January 29, 2026, the Company entered into a securities purchase agreement with a certain institutional accredited investor in connection with a private placement for the offer, issuance and sale of (i) 994,537 pre-funded common stock purchase warrants (the “Pre-Funded Warrants”) to purchase up to 994,537 shares of the Company’s Common Stock (ii) 1,989,074 common warrants (the “Common Warrants”), to purchase up to 1,989,074 shares of Common Stock, for a combined purchase price of \$3.09.

Under the terms of the Pre-Funded Warrants and Common Warrants, a holder will not be entitled to exercise any portion of any Pre-Funded Warrant or Common Warrant, if, upon giving effect to such exercise, the aggregate number of shares of Common Stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder’s affiliates, and any other persons whose beneficial ownership of Common Stock would or could be aggregated with the holder’s or any of the holder’s affiliates for purposes of Section 13(d) or Section 16 of the Securities Exchange Act of 1934, as amended would exceed 4.99% (or, upon election by a holder prior to the issuance of any Pre-Funded Warrants or Common Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise as such percentage ownership is calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Securities and Exchange Commission. A holder may increase or decrease the Beneficial Ownership Limitation to a higher or lower percentage (not to exceed 9.99%), effective 61 days after written notice to the Company.

The gross proceeds to the Company were approximately \$3.1 million, before deducting the placement agent’s fees and related offering expenses. The Company intends to use the net proceeds from the Private Placement for working capital and general corporate purposes.

On January 29, 2026, the Company entered into a warrant inducement offer letter with a certain investor to immediately exercise warrants that were issued to that investor in June 2025 and November 2024 held by such investor at a reduced exercise price of \$2.84, and the Company issued the January Inducement Warrants to the investor to purchase up to a number of shares of common stock equal to 200% of the number of shares of Common Stock issued pursuant to the immediate exercise of the corresponding June 2025 warrants and November 2024 warrants. The January Inducement Warrants have an exercise price of \$2.84 per share, were exercisable immediately upon issuance, and expire upon the five-year anniversary of the date that a resale registration statement related to the January Inducement Warrant issued in the January Inducement Offer becomes effective.

The Company received aggregate gross proceeds of approximately \$1.9 million from the exercise of the June 2025 Warrants and November 2024 Warrants resulting in the issuance of up to an aggregate of 623,585 shares of Common Stock, subject to application of applicable beneficial ownership blockers. As of January 29, 2026, the Company had 1,686,892 shares of common stock issued and outstanding.

The Company also issued to the Placement Agent, or its designees, warrants to purchase up to 48,544 shares of our Common Stock as part of the compensation payable to the Placement Agent in connection with the Private Placement and January Inducement Offering. The Placement Agent Warrants have substantially the same terms as the January Inducement Warrants described above, except that the Placement Agent Warrants have an exercise price of \$5.0985 per share.

As of December 31, 2025, and December 31, 2024, cash, cash equivalents, and marketable securities were \$1.2 million and \$5.1 million, respectively. Our business strategy and ability to fund our operations in the future depend in part on our ability to grow the Aquadex Business by expanding our salesforce, selling our products to hospitals and other healthcare facilities, and controlling costs. We will need to seek additional financing in the future, which, to date, has been through offerings of our equity. We believe that we have sufficient capital to fund our operations through the end of the second quarter of 2026.

Cash Flows from Operating Activities

Net cash used in operating activities was \$10.8 million and \$9.6 million in 2025 and 2024, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by stock-based compensation, depreciation and amortization, and the effects of changes in operating assets and liabilities, including working capital, as well as the net impact of non-cash financing expense and change in the fair value of the warrant liability and warrant financing expense.

Cash Flows from Investing Activities

Net cash used in investing activities was \$90,000 and \$60,000 in 2025 and 2024, respectively. The cash used in investing activities in 2025 and 2024 was for the purchase of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$6.9 million and \$11.0 million in 2025 and 2024, respectively. The cash provided by financing activities in the current year period was the result of proceeds received from the June 2025 financing and the September 2025 Sales Agreement. The cash provided by financing activities in the prior year period was the result of proceeds received from the April 2024, July 2024, and August 2024 financings and from the exercise of warrants from the October 2023 and April 2024 financings.

Contractual Obligations and Commitments

We lease a 23,000 square-foot facility located in Eden Prairie, Minnesota for office and lab 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 \$37,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease.

Capital Resource Requirements

As of December 31, 2025, we did not have any material commitments for capital expenditures.

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. (the "Company") as of December 31, 2025 and 2024, 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, 2025 and 2024, and the results of its operations and cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has recurring losses from operations, an accumulated deficit, expects to incur losses for the foreseeable future and needs additional working capital. These are the reasons that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

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

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

EVALUATION OF WARRANT LIABILITY

Critical Audit Matter Description

As described in Notes 4 and 6 to the consolidated financial statements, the Company has issued or has outstanding, certain common stock and convertible preferred stock warrants which were classified as liabilities as of or during the year ended December 31, 2025. Management determined the proper initial and subsequent classification of the warrants by reviewing the terms and conditions of the issued warrants and applying the applicable accounting guidance, including Accounting Standards Codification (ASC) 480 Distinguishing Liabilities from Equity and ASC 815 Derivatives and Hedging. The Company determined the fair value of convertible preferred stock warrants on the date of issuance, the date of each exercise, and each subsequent measurement date including December 31, 2025, using a Monte Carlo simulation model. The Company determined the fair value of the common stock warrants upon issuance and on each subsequent measurement date using a Monte Carlo simulation model.

We identified the assessment of the measurements of fair value of the warrants as a critical audit matter. Specifically, there was a high degree of subjective auditor judgment, including the involvement of professionals with specialized skills and knowledge, due to the complex valuation methodology that incorporates several assumptions.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- With the assistance of firm personnel having specialized skills and knowledge, we tested the models and methodologies used to calculate the fair value of the warrants at each measurement date including an independent re-calculation.
- Performed audit procedures surrounding management's assumptions utilized in the valuation model.

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

/s/ Baker Tilly US, LLP
Minneapolis, Minnesota
March 11, 2026

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,085	\$ 5,095
Accounts receivable	1,493	1,727
Inventories, net	1,910	1,718
Other current assets	698	315
Total current assets	5,186	8,855
Property, plant and equipment, net	368	478
Operating lease right-of-use asset	293	510
Other assets	271	21
TOTAL ASSETS	\$ 6,118	\$ 9,864
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 2,226	\$ 1,640
Accrued compensation	460	640
Current portion of operating lease liability	261	238
Other current liabilities	85	41
Total current liabilities	3,032	2,559
Warrant liability	389	468
Operating lease liability	67	307
Total liabilities	3,488	3,334
Commitments and contingencies		
Mezzanine Equity		
Series J Convertible Preferred Stock as of December 31, 2025 and December 31, 2024, par value \$0.0001 per share; authorized 600,000 shares, issued and outstanding 137 and 102, respectively	6	2
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2025 and December 31, 2024, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series F convertible preferred stock as of December 31, 2025 and December 31, 2024, par value \$0.0001 per share; authorized 18,000 shares, issued and outstanding 27 and 127 shares, respectively	—	—
Series F-1 convertible preferred stock as of December 31, 2025 and December 31, 2024, par value \$0.0001 per share; authorized 100 shares, issued and outstanding 34 and 0 shares, respectively	—	—
Preferred stock as of December 31, 2025 and December 31, 2024, par value \$0.0001 per share; authorized 39,352,000 shares, none outstanding	—	—
Common stock as of December 31, 2025 and December 31, 2024, par value \$0.0001 per share; authorized 100,000,000 shares, issued and outstanding 1,686,217 and 104,142, respectively	—	—
Additional paid-in capital	318,928	305,366
Accumulated other comprehensive income:		
Foreign currency translation adjustment	8	(47)
Accumulated deficit	(316,312)	(298,791)
Total stockholders' equity	2,624	6,528
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	\$ 6,118	\$ 9,864

See notes to the consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARY
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Net sales	\$ 8,270	\$ 8,740
Cost of goods sold	3,146	3,064
Gross profit	<u>5,124</u>	<u>5,676</u>
Operating expenses:		
Selling, general and administrative	13,518	13,455
Research and development	2,712	3,209
Total operating expenses	<u>16,230</u>	<u>16,664</u>
Loss from operations	(11,106)	(10,988)
Other income (expense), net		
Other income (expense)	10	(80)
Gain on settlement	—	900
Financing expense	(10,553)	(5,607)
Change in fair value of warrant liability	4,133	4,615
Loss before income taxes	<u>(17,516)</u>	<u>(11,160)</u>
Income tax expense	(5)	(5)
Net loss	<u>(17,521)</u>	<u>(11,165)</u>
Deemed dividend attributable to Series J Convertible Preferred Stock	4	541
Net loss attributable to common stockholders	<u>\$ (17,517)</u>	<u>\$ (10,624)</u>
Basic and diluted loss per share	<u>\$ (25.39)</u>	<u>\$ (353.30)</u>
Weighted average shares outstanding – basic and diluted	690,145	31,601
Other comprehensive loss:		
Net loss	\$ (17,521)	\$ (11,165)
Unrealized foreign currency translation adjustment	55	(16)
Total comprehensive loss	<u>\$ (17,466)</u>	<u>\$ (11,181)</u>

See notes to the consolidated financial statements.

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

	Outstanding Shares of Common Stock	Common Stock	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
Balance December 31, 2023	3,866	—	290,647	(31)	(287,626)	2,990
Net loss	—	—	—	—	(11,165)	(11,165)
Unrealized foreign currency translation adjustment	—	—	—	(16)	—	(16)
Stock-based compensation	—	—	478	—	—	478
Issuance of common stock, net	30,336	—	2,051	—	—	2,051
Issuance of common stock from exercise of warrants	69,179	—	5,897	—	—	5,897
Issuance of common stock from conversion of Series J Convertible Preferred Stock	761	—	1,535	—	—	1,535
Series J convertible preferred stock deemed dividend	—	—	541	—	—	541
Reclassification of April 2024 warrants to equity	—	—	4,217	—	—	4,217
Balance December 31, 2024	104,142	\$ —	\$ 305,366	\$ (47)	\$ (298,791)	\$ 6,528
Net loss	—	—	—	—	(17,521)	(17,521)
Unrealized foreign currency translation adjustment	—	—	—	55	—	55
Stock-based compensation	—	—	127	—	—	127
Issuance of common stock, net	396,825	—	3	—	—	3
Issuance of common stock from exercise of warrants	390,524	—	2,055	—	—	2,055
Issuance of Common Stock from ATM offering, net	768,535	—	2,941	—	—	2,941
Issuance of common stock for Preferred F-1 Conversion	26,191	—	—	—	—	—
Series J convertible preferred stock deemed dividend	—	—	(4)	—	—	(4)
Reclassification of Series A warrants to equity	—	—	8,440	—	—	8,440
Balance December 31, 2025	1,686,217	\$ —	\$ 318,928	\$ 8	\$ (316,312)	\$ 2,624

See notes to the consolidated financial statements.

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

	For the years ended December 31,	
	2025	2024
Operating Activities		
Net loss	\$ (17,521)	\$ (11,165)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation	200	310
Stock-based compensation expense	127	478
Change in fair value of warrant liability	(4,133)	(4,615)
Loss on disposal of intangible asset	—	99
Financing expense	10,553	5,607
Amortization of operating lease right-of-use asset	217	—
Changes in operating assets and liabilities:		
Accounts receivable	234	224
Inventory	(192)	279
Other current assets	(528)	(160)
Other assets and liabilities	(173)	(22)
Accounts payable and accrued expenses	406	(626)
Net cash used in operations	(10,810)	(9,591)
Investing activities:		
Purchase of property and equipment	(90)	(60)
Net cash used in investing activities	(90)	(60)
Financing activities:		
Issuance of Common Stock and warrants from offering, net	3,999	2,403
Proceeds from exercise of Series J Convertible Preferred Warrants	—	501
Proceeds from exercise of April 2024 Warrants, net	—	2,246
Issuance of July and August 2024 Common Stock and Warrants, net	—	2,160
Proceeds from warrant inducement in November 2024, net	—	3,364
Proceeds from the exercise of warrants, net	—	288
Issuance of Common Stock from ATM, net	2,941	—
Net cash provided by financing activities	6,940	10,962
Effect of exchange rate changes on cash	55	(16)
Net increase (decrease) in cash, cash equivalents and restricted cash	(3,905)	1,295
Cash, cash equivalents and restricted cash—beginning of year	5,095	3,800
Cash, cash equivalents and restricted cash—end of year	\$ 1,190	\$ 5,095
Supplemental schedule of non-cash activities		
Issuance of Series J Preferred Stock for exercise of Warrants	\$ —	\$ 1,857
Reclassification of April 2024 warrants to equity	\$ —	\$ 4,217
Series A warrants conversion to equity	\$ 8,440	\$ —
Series B warrant exercises	\$ 2,055	\$ —
Issuance of Common Stock for conversion of Series F-1 Preferred Stock	\$ 1,100	\$ —
Deemed dividend on Series J Preferred Stock	\$ 4	\$ 541
Issuance of Common Stock for conversion of Series J Preferred Stock	\$ —	\$ 1,535
Supplemental cash flow information		
Cash paid for income taxes	\$ 7	\$ 7

See notes to the consolidated financial statements.

NUWELLIS, INC. AND SUBSIDIARY

Notes to Consolidated Financial Statements

Note 1—Nature of Business and Significant Accounting Policies

Nature of Business

Nuwellis, Inc. (the “Company”) is a commercial-stage medical device company focused on advancing precision cardiorenal care in critical care settings, through the development, manufacture and commercialization of the Aquadex SmartFlow® system for ultrafiltration therapy. The Aquadex SmartFlow® system is indicated for temporary (up to eight hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more, whose fluid overload is unresponsive to medical management, including diuretics. Nuwellis, Inc. is a Delaware corporation headquartered in Minneapolis with a wholly owned subsidiary in Ireland which we are in the process of dissolving. The Company has been listed on Nasdaq since February 2012.

In August 2016, the Company acquired the business associated with the Aquadex System (the “Aquadex Business”) from a subsidiary of Baxter International, Inc. (“Baxter”) and refocused its strategy to fully devote its resources to the Aquadex Business. On April 27, 2021, the Company announced that it was changing its name from CHF Solutions, Inc. to Nuwellis, Inc. to reflect the expansion of its customer base from treating fluid imbalance resulting from congestive heart failure to also include critical care and pediatrics applications.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company’s chief operating decision-maker, the Company’s chief executive officer, view the Company’s operations and manages its business as a single operating segment. At December 31, 2025 and 2024, long-lived assets were located primarily in the United States (see Note 11 — Segment Reporting).

Going Concern

The Company’s financial statements have been prepared and presented on a basis assuming it continues as a going concern. During the years ended December 31, 2025 and 2024, 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, 2025, the Company had an accumulated deficit of \$316.3 million, and it expects to incur losses for the immediate future. To date, the Company has been funded by equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it will ever operate profitably. These factors raise substantial doubt about the Company’s ability to continue as a going concern through at least twelve months from the report date.

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

During 2021 and through December 31, 2025, the Company closed on underwritten public equity offerings for aggregate net proceeds of approximately \$57.0 million after deducting the underwriting discounts and commissions and other costs associated with the offerings. See Note 4—Stockholders’ Equity for additional related disclosure. The Company will require additional funding to grow its Aquadex Business, which may not be available on terms favorable to the Company, or at all. The Company may receive those funds from the proceeds from future warrant exercises, issuances of equity securities, or other financing transactions.

The Company believes that its existing capital resources will be sufficient to support its operating plan through the end of the second quarter of 2026. However, the Company will seek to raise additional capital to support its growth or other strategic initiatives through debt, equity, or a combination thereof. There can be no assurance we will be successful in raising additional capital.

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Nuwellis, Inc. and its wholly owned subsidiary, Sunshine Heart Ireland Limited which was dissolved as of December 31, 2025. All intercompany accounts and transactions between consolidated entities have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash and term deposits with original maturities of three months or less. The carrying value of these instruments approximates fair value. The balances, at times, may exceed federally insured limits. The Company has not experienced any losses on its cash and cash equivalents.

The Company maintains a corporate credit card program with a financial institution that requires a cash collateral deposit to secure the related credit limit. As of December 31, 2025, the Company had \$105,000 on deposit in a restricted account with the bank. These funds are not available for general corporate purposes and will remain restricted for the duration of the collateral arrangement with the financial institution. Restricted cash is classified as other long-term assets on the consolidated balance sheet based on the expected term of the underlying collateral requirement. The following table provides a reconciliation of cash, cash equivalents, and restricted cash presented in the consolidated statement of cash flows as of December 31, 2025 (in thousands):

Cash and cash equivalents	\$ 1,085
Restricted cash	105
Total cash, cash equivalents, and restricted cash	<u>\$ 1,190</u>

Management evaluates the nature and duration of restrictions each reporting period to determine appropriate classification and disclosure.

Marketable securities

The Company’s marketable securities typically consist of investment-grade, U.S. dollar-denominated fixed and floating-rate debt, which are classified as available-for-sale and included in current assets. Most marketable securities mature within twelve months from their date of purchase and generally are intended to fund current operations. Securities are valued based on market prices for similar assets using third party certified pricing sources. Available-for-sale securities are carried at fair value with unrealized gains and losses reported as a component of shareholders’ equity in accumulated other comprehensive income (loss).

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis and impairment is indicated, it must be determined whether the impairment is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported as a component of shareholders' equity in accumulated other comprehensive gain (loss).

Accounts Receivable

Accounts receivables are unsecured, recorded at net realizable value, and do not bear interest. The Company makes judgments as to its ability to collect outstanding receivables based upon significant patterns of collectability, historical experience, and management's evaluation of specific accounts, and it will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers' financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. To date the Company has not experienced any write-offs or significant deterioration in the aging of its accounts receivable, and therefore, no allowance for doubtful accounts was considered necessary as of December 31, 2025, or December 31, 2024. As of December 31, 2025, three customers represented 14%, 11% and 10% of the total accounts receivable balance. As of December 31, 2024, two customers represented 23% and 11% of the total accounts receivable balance.

Inventories

Inventories are recorded at the lower of cost or net realizable value using the first-in, first-out method. Overhead is allocated to manufactured finished goods inventory based on the normal capacity of the Company's production facilities. Abnormal amounts of overhead, if any, are expensed as incurred. On a regular basis, the Company reviews its inventory and identifies that which is excess, slow moving, and obsolete by considering factors such as inventory levels and expected product life. A reserve is established for any identified excess, slow moving, and obsolete inventory through a charge to cost of goods sold. Inventories consisted of the following as of December 31:

<i>(in thousands)</i>	2025	2024
Finished Goods	\$ 445	\$ 512
Work in Process	88	131
Raw Materials	1,457	1,310
Inventory Reserve	(80)	(235)
Total	<u>\$ 1,910</u>	<u>\$ 1,718</u>

Other Current Assets

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

Property, Plant and Equipment

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

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

Depreciation and amortization expense was \$200,000 and \$310,000 for the years ended December 31, 2025, and 2024, 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 therefore bypassed, and the Company proceeded to measure fair value of the asset group. The Company had contracted with an independent fixed asset appraiser in 2024 to determine the fair value of the asset groups using a combination of the indirect cost method and income method to value the long-lived assets. The Company's fixed asset purchases for fiscal 2025 were immaterial, so the Company was able to utilize the same valuation report as was used in fiscal 2024. There have been no impairment losses recognized for the years ended December 31, 2025 or December 31, 2024.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*. Accordingly, the Company recognizes revenue when its customers obtain control of its products or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. See Note 2 – Revenue Recognition, for additional disclosures. For the year ended December 31, 2025, one customer represented 13.7% of net sales. For the year ended December 31, 2024, two customers represented 14.4% and 11.9% of net sales.

Foreign Currency Translation

Sales and expenses denominated in foreign currencies are translated at average exchange rates in effect throughout the year. Assets and liabilities of foreign operations are translated at period-end exchange rates with the impacts of foreign currency translation recorded in cumulative translation adjustment, a component of accumulated other comprehensive income. Foreign currency transactions gains and losses are included in other expense, net in the consolidated statements of operations and other comprehensive loss.

Stock-Based Compensation

The Company recognizes all share-based payments to employees, directors, and consultants, including grants of stock options and common stock awards, in the consolidated statement of operations and comprehensive loss as an operating expense based on their fair values as established at the grant date. Equity instruments issued to non-employees include common stock awards or warrants to purchase shares of our common stock. These common stock awards or warrants are either fully vested and exercisable at the date of grant or vest over a certain period during which services are provided. The Company expenses the fair market value of fully vested awards at the time of grant and of unvested awards over the period in which the related services are received.

The Company computes the estimated fair values of stock options using the Black-Scholes option pricing model. Market price at the date of grant is used to calculate the fair value of common stock awards.

Stock-based compensation expense is recorded based on awards ultimately expected to vest and is reduced for forfeitures. See Note 5— Stock-Based Compensation, for further information regarding the assumptions used to calculate the fair value of stock-based compensation.

Income Taxes

Deferred income taxes are provided on a liability method, whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences, which are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Loss per Share

Basic loss per share is computed based on the net loss for each period divided by the weighted average number of common shares outstanding. For the years ended December 31, 2025 and December 31, 2024, a net gain of \$4,000 and \$541,000 respectively, was included as a deemed dividend from the Series J Convertible Preferred Stock. (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,	
	2025	2024
Stock options	4,452	78
Warrants to purchase common stock	1,334,937	127,768
Series F convertible preferred stock	10,719	50,419
Series F-1 convertible preferred stock	13,498	—
Series J convertible preferred stock	81	72
Total	<u>1,363,687</u>	<u>178,337</u>

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)	2025	2024
Net loss	\$ (17,521)	\$ (11,165)
Deemed dividend attributable to Series J Convertible Preferred Stock	4	541
Net loss to common shareholders	(17,517)	(10,624)
Weighted average shares outstanding	690,145	31,601
Basic and diluted loss per share	<u>\$ (25.39)</u>	<u>\$ (353.30)</u>

Research and Development

Research and development (R&D) costs include activities related to development, design, and testing improvements of the Aquadex System and potential related new products. These R&D costs also include expenses related to clinical research that the Company may sponsor or conduct to enhance understanding of the product and its use. R&D costs are expensed as incurred. Our sponsored human clinical trials are performed at qualified clinical trial sites and may be supported by outside vendors. Cost associated with setting up each clinical trial site is accrued upon execution of a clinical trial agreement. Expenses related to the performance and management of clinical trials are accrued at the time trial activities occur at the clinical trial sites and outside vendors. While we utilize electronic data capture systems to capture clinical trial data, such data is sometimes incomplete or delayed. In these cases, we are required to estimate work performed in accordance with each clinical trial agreement, including but not limited to the extent of participant enrollment, reported data events, etc. and the extent of supporting services performed in accordance with vendor agreements. Estimates are then adjusted to reflect the actual work performed at each clinical trial site or supporting vendor upon receipt of invoice and confirmation of complete and accurate data entry in the electronic data capture system. Accrued costs may be subject to revisions such as clinical trials, physician-initiated research, or development programs progress and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

On September 11, 2025, the Company entered into a research and development collaboration agreement with Koronis Biomedical Corporation (KBT) to design and develop certain technology having utility in renal replacement therapy for small children and neonates with acute kidney injury, fluid overload and kidney failure. This agreement became effective on September 5, 2025, when KBT received approval of a \$3.0 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 \$600,000, payable in eighteen monthly installments commencing on January 1, 2027. Installments are expensed as Research and Development when due.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The guidance requires expanded interim and annual disclosures of segment information including the disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within segment profit and loss. The guidance is effective for the Company’s fiscal 2024 Form 10-K and interim periods thereafter. The Company has adopted this standard for the year ended December 31, 2024. (see Footnote 11 – Segment Reporting).

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The new guidance is expected to improve income tax disclosures primarily related to the rate reconciliation and income taxes paid information by requiring 1) consistent categories and greater disaggregation of information in the rate reconciliation and 2) income taxes paid disaggregated by jurisdiction. The guidance is effective on a prospective basis, although retrospective application and early adoption is permitted. The Company has adopted ASU 2023-09 for the annual period ending December 31, 2025. (see Footnote 7 – Income Taxes).

In March 2024, the SEC adopted rules under SEC Release No. 33-11275, *The Enhancement and Standardization of Climate-Related Disclosures for Investors*, which requires the disclosure of material Scope 1 and Scope 2 greenhouse gas emissions and other climate-related topics in annual reports and registration statements. For non-accelerated filers and smaller reporting companies, disclosure requirements will begin phasing in for fiscal years beginning on or after January 1, 2027, subject to legal challenges and the SEC’s voluntary stay of the disclosure requirements. The Company is currently evaluating the impact these rules will have on its consolidated financial statements and related disclosures.

Subsequent Events

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

Note 2 – Revenue Recognition

Net Sales

The Company sells its products in the United States primarily through a direct salesforce. Customers who purchase the Company’s products include hospitals and clinics throughout the United States. In countries outside the United States, the Company sold its products through a limited number of specialty healthcare distributors in Austria, Belarus, Brazil, Colombia, Czech Republic, Germany, Greece, Hong Kong, India, Indonesia, Israel, Italy, Panama, Romania, Singapore, Slovak Republic, Spain, Switzerland, Thailand, United Arab Emirates and the United Kingdom. These distributors resell the Company’s products to hospitals and clinics in their respective geographies. International revenue represents 3% and 4% of net sales for the year ended December 31, 2025, and 2024, respectively.

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, 2025, and 2024. The unfulfilled performance obligations related to these extended service plans are included in deferred revenue, which is included in other current liabilities on the consolidated balance sheets. The majority of the deferred revenue is expected to be recognized within one year.

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

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

Note 3—Property, Plant and Equipment

Property, plant and equipment were as follows:

<i>(in thousands)</i>	December 31, 2025	December 31, 2024
Production Equipment	\$ 1,467	\$ 1,382
Loaners and Demo Equipment	1,554	1,554
Computer Software and Equipment	697	692
Office Furniture & Fixtures	375	375
Leasehold Improvements	253	253
Total	4,346	4,256
Accumulated Depreciation	(3,978)	(3,778)
Total	<u>\$ 368</u>	<u>\$ 478</u>

Depreciation and amortization expense was \$200,000 and \$310,000 for the years ended December 31, 2025, and 2024, respectively.

Note 4—Stockholders' Equity

Series F Convertible Preferred Stock: On November 27, 2017, the Company closed on an underwritten public offering of Series F convertible preferred stock and warrants to purchase shares of common stock. 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 \$7,000,000). Effective for every stock offering or reverse stock split, the conversion price of the Series F convertible preferred stock has been recalculated based on the offering price.

As of July 7, 2025 (the effective date of the most recent reverse stock split), the conversion price of the Series F convertible preferred stock was recalculated to \$397.00. As of December 31, 2025 and December 31, 2024, 27 shares and 127 shares of the Series F convertible preferred stock remained outstanding, respectively.

Series F-1 Convertible Preferred Stock: On June 6, 2025, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series F-1 Convertible Preferred Stock with the State of Delaware. At that time, 100 shares of Series F Preferred Stock were outstanding and owned by the Company's Chief Executive Officer, John L. Erb. Such 100 shares of Series F Preferred Stock were exchanged for Series F-1 Preferred Shares pursuant to a Securities Exchange Agreement between John L. Erb and the Company, dated June 9, 2025.

On June 9, 2025, 66 shares of the Series F-1 Preferred shares were converted into 26,191 shares of the Company's Common Stock. The conversion rate for the 66 Series F-1 Preferred Shares was \$397.00 per share.

As of December 31, 2025, 66 of the series F-1 Preferred shares had been converted to Common Stock and 34 remained outstanding.

April 2024 Offering: On April 30, 2024, the Company closed on a best efforts public offering (the "April 2024 Offering") of 5,728 shares of its common stock, 1,925 shares of its common stock for pre-funded warrants and warrants to purchase up to an aggregate of 76,531 shares of its common stock at a combined public offering price \$352.80 per share. All pre-funded warrants were exercised on the date of the offering. Each share of common stock (or prefunded warrant in lieu thereof) was sold together with one warrant to purchase one and a half shares of common stock. The warrants had an exercise price of \$88.20 per share, were exercisable immediately upon issuance, and will expire five years following the date of issuance. Each whole common warrant entitles the holder thereof to purchase one share of common stock.

The common warrants contained a reset of the exercise price, effective upon the Warrant Stockholder Approval, to a price equal to the lesser of (i) the then exercise price, (ii) the lowest volume weighted average price for the five trading days immediately following the date we effect a reverse stock split in the future and (iii) if we effect a reverse stock split prior to obtaining the approval of the Company's stockholders (the "Warrant Stockholder Approval"), the lowest volume weighted average price for the five trading days immediately following the date we obtain the Warrant Stockholder Approval. The Company secured the Warrant Stockholder Approval on June 6, 2024. Subsequent to June 30, 2024, the number of shares underlying the common warrants were adjusted to 59,484 shares and the exercise price was adjusted to \$104.58 per share. In addition, the common warrants provided for full ratchet anti-dilution adjustment to the exercise price and number of shares underlying the common warrants upon our issuance of our common stock or common stock equivalents at a price per share that is less than the exercise price of the common warrants, subject to certain exemptions. In no event would the exercise price of the common warrants with respect to either adjustment be reduced below a floor price of \$88.20.

The gross proceeds to the Company from the April 2024 Offering, before deducting the placement agent fees and other offering expenses were approximately \$2.7 million.

The warrants offered in this financing were originally classified as a liability on the balance sheet. An independent valuation of the warrants was performed and reviewed with management, and the valuation at issuance was \$7.8 million. The warrants had down-round protection and the price was reset from the June 2024 reverse stock split, which was effective July 8, 2024, and from the July 2024 and the August 2024 offerings. At the August 2024 offering, the exercise price of these warrants was adjusted to \$88.20, which represented the floor price on these warrants. As the price floor was hit, there was no further down-round protection. The warrants were re-evaluated and classified as equity as of September 30, 2024. During the year, there were 65,186 warrants exercised at a weighted average exercise price of \$93.66. The warrants are fair valued on the date of exercise and the adjustment to fair value is recorded to Additional Paid in Capital. There were 65,186 warrants converted to equity resulting in \$5.6 million of net proceeds to Additional Paid in Capital.

July 2024 Offering: On July 25, 2024, the Company closed on an offering whereby it entered into a definitive securities purchase agreement with certain institutional investors for the purchase and sale of 11,175 shares of the Company's common stock at a price of \$178.08 per share of common stock in a registered direct offering priced at-the-market under Nasdaq rules (the "July 2024 Offering").

In addition, in a concurrent private placement, the Company issued the investors warrants to purchase up to 22,353 shares of common stock. The warrants have an exercise price of \$167.58 per share, were exercisable immediately following the date of issuance and have a term of five years from the date of issuance. The warrants issued in this offering were concluded to be equity classified.

Roth Capital Partners, LLC acted as the placement agent in the July 2024 Offering.

The gross proceeds to the Company from the registered direct offering and the concurrent private placement were approximately \$2.0 million. After deducting placement agent fees and other offering expenses payable by the Company, net proceeds were approximately \$1.5 million. The Company used the net proceeds from the offering for working capital and for general corporate purposes.

August 2024 Offering: On August 23, 2024, the Company entered into a placement agency agreement with Ladenburg Thalmann & Co. Inc. (the "Placement Agent") and a securities purchase agreement with certain purchasers pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate of 11,508 shares of the Company's common stock, \$0.0001 par value per share, at a purchase price of \$77.49 per share and accompanying common warrant (the "August 2024 Offering").

The shares offered in the August 2024 Offering were sold pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-280647), including a base prospectus contained therein, which was originally filed with the SEC on July 1, 2024, and was declared effective by the SEC on July 9, 2024, and a related prospectus supplement, dated August 23, 2024, related to the August 2024 Offering.

In a concurrent private placement the Company also agreed to sell and issue to the Purchasers, warrants to purchase up to 11,508 shares of the Company's common stock. The common warrants have an exercise price of \$72.24 per share, were immediately exercisable and expire on the fifth anniversary on the effective date of the registration statement to be filed for the purpose of registering the shares of the Company's common stock underlying the common warrants. The warrants issued in this offering were concluded to be equity classified.

The gross proceeds from the August 2024 Offering, before deducting the Placement Agent's fees and expenses and other offering expenses payable by the Company and excluding the net proceeds, if any, from the exercise of the common warrants or August Placement Agent Warrants (as defined below), was approximately \$631,000. The August 2024 Offering closed on August 26, 2024. The Company also issued to the Placement Agent, or its designees, warrants to purchase up to 348 shares of the Company's common stock as part of the compensation payable to the Placement Agent in connection with this offering (the "August Placement Agent Warrants"). The August Placement Agent Warrants were not registered pursuant to the prospectus supplement and the accompanying prospectus. The August Placement Agent Warrants have substantially the same terms as the common warrants described above, except that the August Placement Agent Warrants have an exercise price of \$127.86 per share and will expire August 23, 2029.

November 2024 Warrant Inducement: On November 5, 2024, the Company announced the entry into definitive agreements for the immediate exercise of certain outstanding warrants issued by the Company in the April 2024 Offering to purchase up to an aggregate of 43,632 shares of the Company's common stock at their current exercise price of \$88.20 per share for total gross proceeds of approximately \$3.8 million, prior to deducting inducement agent fees and estimated offering expenses. In consideration for the immediate exercise of the April 2024 Offering warrants, the Company issued Series I common stock purchase warrants (the "Series I Warrants") and Series II common stock purchase warrants (the "Series II Warrants") to purchase up to an aggregate of 87,274 shares of common stock. The Company determined the inducement to be a modification of the April Warrants. The change in fair value associated with the inducement was \$1.4 million, which was recorded as an offering expense within additional paid in capital. The Series I Warrants have an exercise price of \$81.48, are exercisable six (6) months from the date of issuance, and have a term of five (5) years from the date of exercisability. The Series II Warrants have an exercise price of \$81.48, are exercisable six (6) months from the date of issuance, and have a term of two (2) years from the date of exercisability. The Series I Warrants and Series II Warrants are fixed priced and do not contain any variable pricing features. The Company also issued to the Placement Agent, or its designees, warrants to purchase up to 1,312 shares of the Company's common stock as part of the compensation payable to the Placement Agent in connection with the warrant inducement. The Series I Warrants and Series II Warrants described above were offered in a private placement pursuant to an applicable exemption from the registration requirements under Section 4(a)(2) of the Securities Act of 1933 (the "Securities Act"), and have not been registered under the Securities Act, and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission (the "SEC") or an applicable exemption from such registration requirements. The securities were offered only to accredited investors. The Company filed a registration statement with the SEC covering the resale of the shares of common stock issuable upon exercise of the Series I Warrants, Series II Warrants, and the warrants issued to the Placement Agent in the August 2024 offering and November 2024 warrant inducement.

Underwriter and Placement Agent Fees: In connection with the offerings described above, the Company paid the underwriter or placement agent, as applicable, an aggregate cash fee of either 7% or 8% of the aggregate gross proceeds raised in each of the offerings, except with respect to the issuances made pursuant to the At-the-Market Program, for which the placement fee was equal to 3% of the aggregate gross proceeds.

June 2025 Offering: On June 10, 2025, the Company announced the closing of its public offering of 61,444 shares of its Common Stock, pre-funded warrants to purchase 335,381 shares of Common Stock (all pre-funded warrants were exercised on this date), in each case with accompanying Series A Warrants to purchase up to 1,190,480 shares of Common Stock, Series B Warrants to purchase up to 396,829 shares of Common Stock and Placement Warrants to purchase up to 11,903 shares of Common Stock with gross proceeds of approximately \$5.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants. The public offering price per share of Common Stock and accompanying warrants is \$12.60 per share and accompanying warrants, and the public offering price per pre-funded warrant and accompanying warrants is \$12.5958 per pre-funded warrant and accompanying warrants. Each pre-funded warrant has an exercise price of \$0.0042 per pre-funded warrant and was immediately exercisable. The Series B Warrants have an exercise price of \$12.60 and will be exercisable for a period of five years following the receipt of stockholder approval which was obtained on August 4, 2025, as required by the applicable rules and regulations of Nasdaq. The Series A Warrants contain a one-time reset of the exercise price in the event that the Company implemented the 2025 Reverse Stock Split equal to the greater of: (i) 20% of the combined public offering price per share of Common Stock and accompanying warrants in the offering and (ii) the lowest daily volume weighted average price for the five trading days immediately following the date of the implementation of the 2025 Reverse Stock Split. After the reverse stock split effectuated on July 3, 2025, the reset exercise price of the Series A warrants was set at \$7.00 per share and there were no further contractual exercise price adjustments following the reverse split. The Series B Warrants include a zero cash exercise option allowing holders of a Series B Warrant the right to receive, without payment of any additional cash to the Company, an aggregate number of shares equal to the number of shares of Common Stock that would be issuable upon a cash exercise of such Series B Warrants.

The Series A and B warrants offered in this financing were determined to be classified as a liability on the consolidated balance sheet. An independent valuation of the warrants was performed and reviewed with management. The Series A warrants were valued using the Monte Carlo Simulation Model utilizing US Treasury Rates, Volatility rates, Common Stock price and assumptions around date and likelihood of a reverse split exercise price adjustment. The Series B warrants were valued using the Common Stock price given the zero-exercise price. Subsequently, the liability associated with the Series A Warrants was reclassified as equity and a majority of the liability associated with the Series B Warrants was removed as these were exercised into common stock.

Reverse Stock Split: On June 19, 2025, the Board approved the 2025 Reverse Stock Split. On July 2, 2025, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation (the “Certificate of Amendment”) to effect the 2025 Reverse Stock Split, which became effective as of 5:00 p.m. Eastern Time on July 3, 2025, and the Company’s Common Stock began trading on a split-adjusted basis when the market opened on July 7, 2025. When the 2025 Reverse Stock Split became effective, every forty-two shares of the Company’s issued and outstanding Common Stock (and such shares held in treasury) automatically converted into one share of Common Stock, without any change in the par value per share. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the conversion of the Company’s outstanding shares of preferred stock and exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of Common Stock and the number of shares reserved for issuance pursuant to the Company’s equity incentive compensation plans. Any fraction of a share of Common Stock that was created as a result of the 2025 Reverse Stock Split was rounded down to the next whole share and the stockholder received cash equal to the market value of the fractional share, determined by multiplying such fraction by the closing sales price of the Company’s Common Stock as reported on Nasdaq on the last trading day before the 2025 Reverse Stock Split becomes effective. All share and per-share amounts have been retroactively adjusted to reflect the reverse stock splits for all periods presented.

At The Market Offering Agreement: On September 3, 2025, the Company entered into an At The Market Offering Agreement with Ladenburg Thalmann & Co. Inc. pursuant to which the Company may sell shares of the Company’s Common Stock, from time to time, at its option, through or to Ladenburg, as sales agent or principal. Sales of the Company’s Common Stock made pursuant to the Sales Agreement, were made under the Company’s Registration Statement on Form S-3 (File No. 333-280647) and the prospectus supplement filed on September 3, 2025 with the Securities and Exchange Commission, in sales deemed to be “at the market offerings” as defined in Rule 415 promulgated under the Securities Act, initially having an aggregate offering price of up to \$4,650,000. Ladenburg will use its commercially reasonable efforts to sell the Common Stock from time to time, based upon the Company’s instructions (including any price, time, or size limits or other customary parameters or conditions the Company may impose). As of December 31, 2025, the Company had sold 768,535 Common Shares for net proceeds of approximately \$2.9 million.

The Company is not obligated to make any sales of Common Stock under the Sales Agreement, and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. The offering of Common Stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. The Company is obligated to pay Ladenburg an aggregate sales agent commission of up to 3.0% of the gross proceeds of the sale price for Common Stock sold under the Sales Agreement. The Company has also provided Ladenburg with customary indemnification rights and expense reimbursements for up to \$50,000 of expenses in addition to ongoing diligence expenses. The representations, warranties and covenants contained in the Sales Agreement were made only for purposes of the Sales Agreement as of specific dates indicated therein, were solely for the benefit of Ladenburg and to allocate risk between the Company and Ladenburg, and as a result should not be relied on and may be subject to limitations agreed upon by the parties.

Note 5— Stock-Based Compensation

Stock Options and Restricted Stock Awards

The Company has various share-based compensation plans, including the Company’s 2017 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 \$127,000 and \$478,000 during the years ended December 31, 2025, and 2024, respectively. The following table summarizes the stock-based compensation expense that was recognized in the consolidated statements of operations for the years ended December 31, 2025, and 2024.

<i>(in thousands)</i>	2025	2024
Selling, general and administrative	\$ 130	\$ 464
Research and development	(3)	14
Total	\$ 127	\$ 478

The majority of the common stock awards and options to purchase common stock vest on the anniversary of the date of grant, with vesting terms ranging 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:

	2025		2024	
	Options Outstanding	Weighted Average Exercise Price	Options Outstanding	Weighted Average Exercise Price
Beginning Balance	78	\$ 12,826.50	55	\$ 18,580.00
Granted	4,409	21.37	28	1,014.30
Exercised	—	—	—	—
Forfeited/expired	(39)	41,512.05	(4)	366,122.31
Outstanding at December 31	4,452	\$ 51.11	78	\$ 12,826.50
Vested at December 31	2,381	\$ 68.53	46	\$ 4,189.18

	2025		2024	
	Options Outstanding	Weighted Average Fair Value	Options Outstanding	Weighted Average Fair Value
Beginning Balance	78	\$ 11,834.31	55	\$ 17,178.94
Granted	4,409	19.23	28	920.22
Exercised	—	—	—	—
Forfeited/expired	(39)	47,018.11	(4)	9,163.04
Outstanding at December 31	4,452	\$ 47.15	78	\$ 11,834.31
Vested at December 31	2,381	\$ 63.28	46	\$ 3,965.77

For options outstanding and vested at December 31, 2025 and 2024, the weighted average remaining contractual life was 8.21 years and 8.47 years, respectively. There were no option exercises in 2025 or 2024. Intrinsic value for vested options in 2025 and 2024 was \$0. The total fair value of options that vested in 2025 and 2024 was \$58,162, and \$174,399, respectively, at the fair value of the options as of the date of grant.

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

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

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

	2025	2024
Expected dividend yield	0%	0%
Risk-free interest rate	3.90%	3.94%
Expected volatility	137.35%	138.70%
Expected life (in years)	5.50	5.51

The weighted-average fair value of stock options granted in 2025 and 2024 was \$19.23 and \$ 920.22, respectively. As of December 31, 2025, the total compensation cost related to all non-vested stock option awards not yet recognized was approximately \$51,000 and is expected to be recognized over the remaining weighted-average life of 0.36 years.

Warrants: Warrants to purchase 1,334,937 and 127,768 shares of common stock were outstanding on December 31, 2025 and 2024, respectively. Exercisable warrants were 1,334,937 and 39,182 on December 31, 2025 and 2024, respectively. As of December 31, 2025, warrants outstanding were exercisable at prices ranging from \$7.00 to \$36,750 per share and are exercisable over a period ranging from immediately to 4.44 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.

All cash equivalents and marketable securities are considered Level 1 measurements for all periods presented.

The fair value of the Company's common and preferred stock warrant liabilities related to the warrants issued in the October 2022, October 2023, April 2024 and June 2025 public offerings were calculated using a Monte Carlo valuation model and were classified as Level 3 in the fair value hierarchy.

The following is a roll-forward of the fair value of Level 3 warrants:

<i>(in thousands)</i>	<u>2025</u>
Balance at December 31, 2023	\$ 2,843
Exercise of Series J warrants	(1,357)
April 24, 2024, issuance of common warrants	7,813
Exercise of April 2024 warrants	(1,373)
Reclassification of April 2024 warrants to equity	(2,844)
Change in fair value	(4,614)
Balance at December 31, 2024	<u>\$ 468</u>
June 10, 2025 issuance of common warrants	14,547
Reclassification of Series A warrants to equity	(8,439)
Exercise of Series B warrants	(2,054)
Change in fair value	(4,133)
Balance at December 31, 2025	<u>\$ 389</u>

Fair values were calculated using the following assumptions:

	<u>2025</u>	<u>2024</u>
Common Stock Price	\$3.35-\$39.48	\$46.62-\$896.70
Risk-free interest rates, adjusted for continuous compounding	3.68%-4.08%	3.58%-5.05%
Term (years)	1.03-5.0	1.78-5.00
Expected volatility	144%-189.1%	151.90%-116.80%
Dates and probability of future equity raises	various	various

A significant change in the inputs used for the Monte Carlo valuation models, such as the expected volatility, risk-free interest rate, or probability of future equity financings, in isolation, would result in significantly higher or lower fair value measurements. In combination, changes in these inputs could result in a significantly higher or lower fair value measurement if the input changes were to be aligned or could result in a minimally higher or lower fair value measurement if the input changes were of a compensating nature.

Note 7—Income Taxes

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

<i>(in thousands)</i>	<u>2025</u>	<u>2024</u>
Domestic	\$ (17,540)	\$ (11,190)
Foreign	24	30
Loss before income taxes	<u>\$ (17,516)</u>	<u>\$ (11,160)</u>

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

<i>(in thousands)</i>	<u>2025</u>	<u>2024</u>
Current:		
United States and state	\$ —	\$ —
Foreign, net	(5)	(5)
Deferred:		
United States and state	—	—
Foreign	—	—
Total income tax expense	<u>\$ (5)</u>	<u>\$ (5)</u>

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

<i>(in thousands)</i>	<u>2025</u>		<u>2024</u>	
	<u>Amount</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>
Statutory federal income tax benefit	\$ 3,678	21.00%	\$ 2,343	21.00%
State tax benefit, net of federal taxes	364	2.08	321	2.88
Foreign tax	(1)	(0.01)	(1)	(0.01)
Warrant valuation expense	(2,216)	(12.65)	(1,178)	(10.56)
Change in warrant liability	868	4.95	969	8.68
Other	(167)	(0.95)	(506)	(4.53)
Valuation allowance (increase) decrease	(2,531)	(14.45)	(1,953)	(17.50)
Total income tax expense	<u>\$ (5)</u>	<u>(0.03)%</u>	<u>\$ (5)</u>	<u>(0.04)%</u>

Deferred taxes consist of the following as of December 31:

<i>(in thousands)</i>	<u>2025</u>	<u>2024</u>
Deferred tax assets:		
Noncurrent:		
Accrued compensation	\$ 3	\$ 90
Stock-based compensation	23	84
Net operating loss carryforward	55,673	50,749
Other	120	119
Intangibles	446	2,692
R&D credit carryforward	531	531
Total deferred tax assets	<u>56,796</u>	<u>54,265</u>
Less: valuation allowance	(56,796)	(54,265)
Total	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2025, the Company had federal net operating loss (“NOL”) carryforwards of approximately \$240.4 million and state NOL carryforwards of \$77.7 million. Approximately \$118.9 million of federal NOL carryforwards will expire between 2026 and 2038. Pursuant to the Tax Cuts and Jobs Act of 2017, NOLs generated after 2017 of approximately \$121.5 million do not expire. The expiration of state NOL carryforwards will vary by jurisdiction. In addition, future utilization of NOL carryforwards in the U.S. may be subject to certain limitations under Section 382 of the Internal Revenue Code. The Company does not have any foreign loss carryovers.

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of the deferred tax assets. The Company has established a valuation allowance for U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying consolidated financial statements. For the years ended December 31, 2025 and 2024, the valuation allowance increased by \$2.5 million and \$2.0 million, respectively. The current year increase was primarily due to the federal and state net operating losses generated.

Income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign for the year ended December 31, 2025 was as follows:

<i>(in thousands)</i>	<u>2025</u>	<u>2024</u>
Federal	\$ —	\$ —
State	—	—
Ireland	7	7
Total income taxes paid	<u>\$ 7</u>	<u>\$ 7</u>

During 2025 and 2024, the Company believes it experienced an ownership change as defined in Section 382 of the Internal Revenue Code, which will limit the ability to utilize the Company’s net operating losses (NOLs). The Company may have experienced additional ownership changes in earlier years further limiting the NOL carryforwards that may be utilized. The Company has not yet completed a formal Section 382 analysis. The general limitation rules allow the Company to utilize its NOLs subject to an annual limitation that is determined by multiplying the federal long-term tax-exempt rate by the Company’s value immediately before the ownership change.

The accounting guidance related to uncertain tax positions prescribes a recognition threshold and measurement attribute for recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company had no material uncertain tax positions as of December 31, 2025 or 2024.

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, 2025 and 2024, the Company recorded no accrued interest or penalties related to uncertain tax positions.

The tax years ended December 31, 2022 through December 31, 2025 remain open to examination by the Internal Revenue Service and by the various states where the Company is subject to taxation. Additionally, the returns of the Company's Irish subsidiary are subject to examination by tax authorities for the tax years ended December 31, 2022 and subsequent years.

Note 8—Operating Leases

The Company leases a 23,000 square foot facility located in Eden Prairie, Minnesota for office and lab 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 \$36,000. The lease contains provisions for annual inflationary adjustments. Rent expense is being recorded on a straight-line basis over the term of the lease. Beginning on April 1, 2022, the annual base rent was \$10.50 per square foot, subject to annual increases of \$0.32 to \$0.34 per square foot thereafter.

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

<i>(in thousands)</i>	<u>2025</u>	<u>2024</u>
Operating lease cost	\$ 264	\$ 257
Variable lease cost	183	138
Total	\$ 447	\$ 395

Variable lease costs consist primarily of taxes, insurance, and common area or other maintenance costs for our leased office and lab space.

Maturities of our lease liability for the Company's operating lease are as follows as of December 31:

<i>(in thousands)</i>	<u>2025</u>
2026	273
2027	46
Total lease payments	319
Less: Interest	(12)
Present value of lease liability	\$ 307
Less: Current Portion	(240)
Non-current lease liability	\$ 67

As of December 31, 2025 and 2024, the remaining lease terms were 1.25 and 2.25 years, respectively, and discount rates were 6.25% and 6.25% respectively. For the years ended December 31, 2025, and 2024, the operating cash outflows from the Company's operating lease for office and manufacturing space were \$265,000 and \$257,000, respectively.

Note 9—Commitments and Contingencies

Employee Retirement Plan

The Company has a 401(k) plan that provides a retirement benefit to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations, with the Company matching a portion of the employees' contributions at the discretion of the Company. Matching contributions totaled \$128,000 and \$88,000 for the years ended December 31, 2025, and 2024, respectively.

International Exit

On August 7, 2025, the Company announced its decision to exit substantially all of its international operations in order to focus exclusively on the U.S. market—where the Company is seeing the strongest growth and clinical demand. With expanding traction in U.S. cardiac surgery and pediatric programs, and a rising opportunity in the hospital-based outpatient space, the Company is streamlining to prioritize investment in markets where it can have the most immediate and long-term impact. As of December 31, 2025, the Company has accrued approximately \$246,000 in contractual exit fees and product repurchase obligations with certain of its former international distributors. This amount is included in “Accounts payable and accrued liabilities” line on the Consolidated Balance Sheet. These accrued contractual exit fees and product repurchase obligations will be substantially paid out by the end of the first quarter of fiscal 2026.

Technology License Fee

On September 11, 2025, the Company entered into a research and development collaboration agreement with Koronis Biomedical Corporation (KBT) to design and develop certain technology having utility in renal replacement therapy for small children and neonates with acute kidney injury, fluid overload and kidney failure. This agreement became effective on September 5, 2025, when KBT received approval of a \$3.0 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 \$600,000, payable in eighteen monthly installments commencing on January 1, 2027. The Company can unilaterally terminate the Agreement at any time for any reason making future installments avoidable. No unconditional obligation exists until each installment becomes due. Installments are expensed as Research and Development only when due. Discounting is not applied because the installments do not represent a present obligation.

Note 10—Related Party Transactions

There were no related party transactions requiring disclosure during the years ended December 31, 2025 and 2024.

Note 11—Segment Reporting

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker (“CODM”), or decision-making group, in deciding how to allocate resources in assessing performance. Nuwellis has one reportable segment: fluid overload. The Company is a medical technology company focused on developing, manufacturing, and commercializing a medical device used in ultrafiltration therapy, including the Aquadex FlexFlow® and the Aquadex SmartFlow® systems (collectively the “Aquadex System”). The Company recognizes this medical device business as one reporting segment. The Company’s CODM is the chief executive officer.

The accounting policies of the fluid overload segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the fluid overload segment based on net loss, which is reported on the statement of operations as consolidated net loss. The measure of segment assets is reported on the balance sheet as total consolidated assets. The company does not have any intra-entity sales or transfers.

The CODM uses cash forecast models in deciding how to invest into the fluid overload segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment and in establishing management’s compensation, along with cash forecast models.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025, and 2024:

<i>(in thousands)</i>	Year Ended December 31,	
	2025	2024
Revenue	\$ 8,270	\$ 8,740
Gross Profit	5,124	5,676
Gross profit %	62.0%	64.9%
Operating expenses:		
General and administrative	5,803	5,637
Sales and Marketing	6,703	6,254
Development	1,296	1,645
Clinical, Quality, Regulatory	2,301	2,650
Total Expenses	16,103	16,186
Stock-Based Compensation	127	478
Other Expense	6,415	177
Net loss	(17,521)	(11,165)

Note 12—Subsequent Events

January Private Placement

On January 29, 2026, the Company entered into a securities purchase agreement with a certain institutional accredited investor in connection with a private placement for the offer, issuance and sale of (i) 994,537 pre-funded common stock purchase warrants to purchase up to 994,537 shares of the Company’s common stock, \$0.0001 par value and (ii) 1,989,074 common warrants, and together with the Pre-Funded Warrants, to purchase up to 1,989,074 shares of Common Stock and together with the Pre-Funded Warrant Shares and the Pre-Funded Warrants, for a combined purchase price of \$3.09.

Under the terms of the Pre-Funded Warrants and Common Warrants, a holder will not be entitled to exercise any portion of any Pre-Funded Warrant or Common Warrant, if, upon giving effect to such exercise, the aggregate number of shares of Common Stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder’s affiliates, and any other persons whose beneficial ownership of Common Stock would or could be aggregated with the holder’s or any of the holder’s affiliates for purposes of Section 13(d) or Section 16 of the Securities Exchange Act of 1934, as amended would exceed 4.99% (or, upon election by a holder prior to the issuance of any Pre-Funded Warrants or Common Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise as such percentage ownership is calculated in accordance with Section 13(d) of the Exchange Act and the applicable regulations of the Securities and Exchange Commission. A holder may increase or decrease the Beneficial Ownership Limitation to a higher or lower percentage (not to exceed 9.99%), effective 61 days after written notice to the Company.

The Private Placement Purchase Agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company, other obligations of the parties and termination provisions.

The Securities were issued to an institutional accredited investor in a private placement pursuant to Section 4(a)(2) and/or Regulation D promulgated under the Securities Act of 1933, as amended.

The gross proceeds from the January Private Placement to the Company were approximately \$3.1 million, before deducting the placement agent’s fees and related offering expenses. The Company intends to use the net proceeds from the Private Placement for working capital and general corporate purposes.

Registration Rights Agreement

In connection with the January Private Placement, the Company entered into a registration rights agreement with the Purchaser, which required the Company to file with the SEC a registration statement to register for resale the Securities sold in the Private Placement within fifteen (15) days of January 29, 2026 and cause such registration statement to become effective within forty-five (45) days (or sixty (60) days if the SEC notifies the Company that it will “review” the registration statement). Such registration statement was filed on February 4, 2026 and made effective on February 9, 2026.

Warrant Inducement

As previously reported, on June 10, 2025, the Company issued and sold, in a registered public offering, 61,444 shares of its Common Stock, and pre-funded warrants to purchase 335,381 shares of Common Stock, in each case with accompanying Series A Warrants to purchase up to 1,190,480 shares of Common Stock and Series B Warrants to purchase up to 396,829 shares of Common Stock with gross proceeds of approximately \$5.0 million (the Series A Warrants and Series B Warrants, collectively the “June 2025 Warrants”). Also, as previously reported, the Company issued and sold, in a best efforts registered public offering, 5,728 shares of the Company’s Common Stock, pre-funded warrants to purchase up to an aggregate of 1,925 shares of Common Stock and common warrants (the “April 2024 Warrants”) to purchase up to an aggregate of 11,480 shares of Common Stock. Also, as previously reported, on November 5, 2024, the Company entered into warrant inducement offer letters with certain investors to immediately exercise approximately 1.9 million of the April 2024 Warrants held by such investors and the Company issued to the investors a new Series I Common Stock Purchase Warrant and a new Series II Common Stock Purchase Warrant, in each case, to purchase up to a number of shares of common stock equal to 100% of the number of shares of Common Stock issued pursuant to the immediate exercise of the corresponding April 2024 Warrants (the “November 2024 Warrants”).

On January 29, 2026, the Company entered into a warrant inducement offer letter with a certain investor to immediately exercise the remaining June 2025 Warrants and November 2024 Warrants held by such investor at a reduced exercise price of \$2.84 and the Company issued to the investor a new Common Stock Purchase Warrant to purchase up to a number of shares of common stock equal to 200% of the number of shares of Common Stock issued pursuant to the immediate exercise of the corresponding June 2025 Warrants and November 2024 Warrants. The January Inducement Warrants have an exercise price of \$2.84 per share, will be exercisable immediately upon issuance, and will expire upon the five-year anniversary of the date that a resale registration statement related to the January Inducement Warrant issued in the January Inducement Offer becomes effective, which occurred on February 9, 2026.

The Company received aggregate gross proceeds of approximately \$2 million from the exercise of the June 2025 Warrants and November 2024 Warrants resulting in the issuance of up to an aggregate of 623,585 shares of Common Stock, subject to application of applicable beneficial ownership blockers. As of January 29, 2026, the Company had 1,686,892 shares of common stock issued and outstanding.

The Company also issued to the Placement Agent, or its designees, warrants to purchase up to 48,544 shares of our Common Stock as part of the compensation payable to the Placement Agent in connection with the January Private Placement and January Inducement Offering (the “January Inducement Warrants”). The Placement Agent Warrants have substantially the same terms as the January Inducement Warrants described above, except that the Placement Agent Warrants have an exercise price of \$5.0985 per share.

Rendiatech Transaction

On January 29, 2026, the Company entered into a Securities Purchase Agreement (“**Rendiatech Purchase Agreement**”) with Rendiatech, Ltd., an Israeli company (“**Rendiatech**”) and the sellers named therein (the “**Rendiatech Sellers**”) whereby the Company will purchase all of the issued and outstanding ordinary shares of Rendiatech (the “**Transaction**”) upon the completion of certain closing conditions, including receipt of approval of the Transaction from the Israeli Tax Authority. Rendiatech has no commercial operations and was formed on March 30, 2025 to acquire certain assets of RenalSense Ltd. following its bankruptcy proceedings; the Company is acquiring Rendiatech primarily to gain access to such assets. In consideration, upon closing, the Company agreed to: (i) pay \$125,000 cash at closing, (ii) issue 150,000 shares of the Company’s Common Stock, and (iii) issue stock options to purchase 30,000 shares of the Company’s Common Stock as set forth in the Rendiatech Purchase Agreement. Additionally, the Company agreed to pay (i) to the Sellers’ Representative, for the benefit of the **Rendiatech** Sellers, \$125,000 on or prior to December 31, 2026, (ii) \$250,000 on the earlier to occur of: (a) the Commercial Regulatory Clearance Date (as defined in the Rendiatech Purchase Agreement) or (b) December 31, 2027, and (iii) an earn-out royalty payment equal to nine percent (9%) of gross sales recognized by the Company on the commercial sale of Rendiatech’s real-time urine flow and kidney monitoring technology products known as “Clarity RMS” and “Clarity Prime” (the “**Earn-Out Royalty**”), until the Company’s aggregate payments of the Earn-Out Royalty equal \$2,000,000. The **Rendiatech** Purchase Agreement contains customary representations, warranties, covenants and indemnification obligations for a transaction of this type.

Executive Transition

Robert B. Scott resigned from the Company as Chief Financial Officer effective October 24, 2025. Carisa Schultz was appointed by the Company’s board of directors to serve as Chief Financial Officer, the Principal Financial Officer, and Principal Accounting Officer effective, February 2, 2026.

Hutton Litigation

On February 11, 2026, E.F. Hutton & Co. (“**Hutton**”) filed a complaint against the Company with the Supreme Court of the State of New York. The complaint alleges, among other things, that the Company breached its engagement letter with Hutton to act as its exclusive placement agent for the Company’s registered securities offerings. The complaint seeks compensatory damages, punitive damages, interest, costs and attorneys’ fees. The Company intends to vigorously defend itself in this matter; however, in light of, among other things, the preliminary stage of the litigation, the Company is unable to provide any assurances as to the ultimate outcome of the lawsuit and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome. The Company has not yet filed an answer to the complaint.

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, 2025, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of December 31, 2025. The Certifying Officers based their conclusion on the fact that the Company has identified two material weaknesses in controls over financial reporting, as detailed in this Annual Report on Form 10-K. In light of this fact, management expects to perform additional analyses, reconciliations, and remediations.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; 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, 2025, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. As reported herein, we identified two material weaknesses that continued to exist at December 31, 2025. Based on this conclusion, management has concluded that our internal control over financial reporting was ineffective as of December 31, 2025.

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

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

Material Weakness in Internal Control Over Financial Reporting

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

Remediation Plans

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

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter ended December 31, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, as a result of the identified material weaknesses, changes in our internal control over financial reporting will occur.

Item 9B. Other Information.

None of the Company's directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the Company's three months ended December 31, 2025, as such terms are defined under Item 408(a) of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is set forth under the following captions in our proxy statement to be filed with respect to the 2026 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," "Board Matters — Insider Trading Policy," 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." (excluding the section titled "Pay Versus Performance").

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 Accountant 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	Form	File Number	Incorporated By Reference		Filed Herewith
				Date of First Filing	Exhibit Number	
3.1	Fourth Amended and Restated Certificate of Incorporation	10	001-35312	February 1, 2012	3.1	
3.2	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 13, 2017	3.1	
3.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	May 23, 2017	3.1	
3.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	October 12, 2017	3.1	

3.5	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	January 2, 2019	3.1
3.6	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K/A	001-35312	October 16, 2020	3.1
3.7	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	April 27, 2021	3.1
3.8	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	December 9, 2022	3.1
3.9	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	June 26, 2024	3.1
3.10	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation	8-K	001-35312	July 2, 2025	3.1
3.11	Third Amended and Restated Bylaws	10-Q	001-35312	November 12, 2024	3.13
3.12	Amendment to Third Amended and Restated Bylaws	10-Q	001-35312	November 12, 2024	3.14
3.13	Form of Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	S-1/A	001-35312	November 17, 2017	3.7
3.14	Certificate of Designation of Preferences, Rights and Limitations of Series I Convertible Preferred Stock	8-K	001-35312	October 18, 2022	3.1
3.15	Certificate of Designation of Preferences, Rights and Limitations of Series F-1 Convertible Preferred Stock	8-K	001-35312	June 9, 2025	3.1
4.1	Form of Warrant to purchase shares of common stock	S-1/A	333-221010	November 17, 2017	4.9
4.2	Form of Series 1 and Series 2 Warrant to Purchase Shares of Common Stock	S-1/A	333-209102	February 25, 2019	4.10
4.3	Common Stock Purchase Warrant, dated May 30, 2019, between the Company and Redington, Inc.	10-Q	001-35312	August 8, 2019	4.1
4.4	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated October 23, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	October 23, 2019	4.1

4.5	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.1
4.6	Form of common stock Pre-Funded Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated November 4, 2019, among the Company and the purchasers signatory thereto	8-K	001-35312	November 4, 2019	4.2
4.7	Form of Common Stock Purchase Warrant	S-1/A	333-235385	January 23, 2020	4.15
4.8	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated March 19, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 20, 2020	4.1
4.9	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated March 30, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	March 30, 2020	4.1
4.10	Form of common stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated May 1, 2020, among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	May 4, 2020	4.1
4.11	Form of Warrant to Purchase Shares of Common Stock	S-1/A	333-24145	August 17, 2020	4.19
4.12	Warrant to purchase shares of Common Stock	S-1/A	333-267368	October 13, 2022	4.20
4.13	Form of Warrant to purchase shares of common stock	S-1/A	333-274610	September 29, 2023	4.13
4.14	Form of Warrant to Purchase Shares of Common Stock	8-K	001-35312	May 1, 2024	4.1
4.15	Form of Pre-Funded Warrant to Purchase Shares of Common Stock	8-K	001-35312	May 1, 2024	4.2
4.16	Form of Common Warrant	8-K	001-35312	July 25, 2024	4.1
4.17	Form of Common Warrant	8-K	001-35312	August 26, 2024	4.1

4.18	Form of Placement Agent Warrant	8-K	001-35312	August 26, 2024	4.2
4.19	Form of Series I Common Stock Purchase Warrant	8-K	001-35312	November 7, 2024	4.1
4.20	Form of Series II Common Stock Purchase Warrant	8-K	001-35312	November 7, 2024	4.2
4.21	Form of Placement Agent Warrant	8-K	001-35312	November 7, 2024	4.3
4.22	Form of Pre-Funded Warrant to Purchase Shares of Common Stock	S-1	333-287663	May 30, 2025	4.2
4.23	Form of Warrant Agency Agreement with Equiniti Trust Company, LLC.	S-1	333-287663	May 30, 2025	4.3
4.24	Form of Common Warrant to Purchase Shares of Common Stock	S-1/A	333-287663	June 3, 2025	4.4
4.25	Form of Representative Warrant to Purchase Shares of Common Stock	S-1	333-287663	May 30, 2025	4.5
4.26	Form of Common Stock Purchase Warrant	8-K	001-35312	January 30, 2026	4.1
4.27	Form of Pre-Funded Warrant	8-K	001-35312	January 30, 2026	4.2
4.28	Form of January Inducement Warrant	8-K	001-35312	January 30, 2026	4.3
4.29	Description of Securities				X
10.1	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	10.1
10.2	2013 Non-Employee Directors' Equity Incentive Plan†	14A	001-35312	April 5, 2013	App. A

10.3	Form of Stock Option Grant Notice and Option Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	May 29, 2013	10.2
10.4	Form of Restricted Stock Unit Award Grant Notice and Agreement for 2013 Non-Employee Directors' Equity Incentive Plan†	10-K	001-35312	March 20, 2015	10.11
10.5	New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2013	10.1
10.6	First Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.1
10.7	Second Amendment to New-Hire Equity Incentive Plan†	S-8	333-202904	March 20, 2015	99.12
10.8	Third Amendment to New-Hire Equity Incentive Plan†	S-8	333-210215	March 15, 2016	99.13
10.9	Fourth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.4
10.10	Fifth Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	January 18, 2018	10.1
10.11	Sixth Amendment to New-Hire Equity Incentive Plan†	10-Q	001-35312	August 8, 2019	10.2
10.12	Seventh Amendment to New-Hire Equity Incentive Plan†	8-K	001-35312	December 6, 2019	10.1
10.13	Eighth Amendment to New-Hire Equity Incentive Plan†	8-K/A	001-35312	February 25, 2021	10.1
10.14	Form of Stock Option Grant Notice and Option Agreement for New-Hire Equity Incentive Plan†	10-Q	001-35312	November 12, 2013	10.2
10.15	2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.1
10.16	First Amendment to the 2017 Equity Incentive Plan†	14A	001-35312	September 11, 2020	App. A
10.17	Second Amendment to the 2017 Equity Incentive Plan†	10-K	001-35312	March 3, 2023	10.17

10.18	Form of Stock Option Grant Notice and Option Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.2
10.19	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for 2017 Equity Incentive Plan†	8-K	001-35312	May 30, 2017	10.3
10.20	Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.1
10.21	First Amendment to the 2021 Inducement Plan†	8-K	001-35312	April 21, 2022	10.1
10.22	Second Amendment to the 2021 Inducement Plan †	8-K	001-35312	March 1, 2023	10.1
10.23	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Nuwellis, Inc. 2021 Inducement Plan†	8-K	001-35312	May 20, 2021	10.2
10.24	Form of Indemnity Agreement for the Company’s executive officers and directors†	10	001-35312	September 30, 2011	10.1
10.25	Form of Change in Control Agreement for the Company’s executive officers†	10-K	001-35312	March 20, 2015	10.16
10.26	Non-Employee Director Compensation Policy (effective January 1, 2023) †	10-K	001-35312	March 3, 2023	10.27
10.27	Lease Agreement dated October 21, 2011 by and between the Company and Silver Prairie Crossroads, LLC	10	001-35312	December 16, 2011	10.18
10.28	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
10.29	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
10.30	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
10.31	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1

10.32	Letter Agreement dated February 15, 2017 among the Company, Sabby Volatility Warrant Master Fund, Ltd. and Sabby Healthcare Master Fund, Ltd.	8-K	003-35312	February 16, 2017	10.1
10.33	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
10.34	Form of Warrant Reprice Agreement	8-K	001-35312	June 29, 2018	10.1
10.35	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
10.36	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
10.37	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
10.38	Offer Letter, by and between the Company and Nestor Jaramillo, dated April 12, 2019†	10-Q	001-35312	May 9, 2019	10.5
10.39	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
10.40	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
10.41	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
10.42	Form of Securities Purchase Agreement, dated as of November 4, 2019, by and among the Company and the purchasers identified on the signature pages thereto	8-K	001-35312	November 4, 2019	10.1
10.43	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
10.44	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
10.45	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
10.46	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

10.47	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
10.48	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
10.49	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
10.50	Underwriting Agreement, dated as of August 19, 2020, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	August 21, 2020	1.1
10.51	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
10.52	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
10.53	Executive Employment Agreement, dated January 16, 2021, by and between the Company and John L. Erb†	8-K	001-35312	January 19, 2021	10.2
10.54	Offer letter by and between the Company and Neil P. Ayotte, effective as of June 7, 2021†	10-Q	001-35312	August 12, 2021	10.4
10.55	Underwriting Agreement dated September 15, 2021, between the Company and Ladenburg Thalmann & Co. Inc., as the Representative of the several underwriters named in Schedule I thereto.	8-K	001-35312	September 17, 2021	1.1
10.56	Warrant Agency Agreement, dated as of October 18, 2022, between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-35312	October 18, 2022	4.2
10.57	Leak-Out Agreement	S-1/A	333-267368	September 30, 2022	10.70
10.58	Underwriting Agreement dated as of October 14, 2022, by and between Nuwellis, Inc. and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	October 18, 2022	1.1
10.59	Offer Letter by and between Nuwellis, Inc. and Robert B. Scott, effective as of September 2, 2023	8-K	001-35312	August 18, 2023	10.1
10.60	Placement Agency Agreement dated as of October 12, 2023, by and between Nuwellis, Inc., Lake Street Capital Markets, LLC and Maxim Group LLC	8-K	001-35312	October 17, 2023	1.1

10.61	Form of Securities Purchase Agreement	S-1/A	333-274610	September 29, 2023	10.69
10.62	Form of Warrant Agency Agreement	S-1/A	333-274610	September 29, 2023	10.68
10.63	Consulting Agreement dated August 4, 2023 by and between Nuwellis, Inc. and Lynn Blake†	8-K	001-35312	August 8, 2023	10.2
10.64	Form of Warrant Agency Agreement	8-K	001-35312	May 1, 2024	4.3
10.65	Form of Securities Purchase Agreement, dated as of April 26, 2024, by and among Nuwellis, Inc. and the purchasers identified on the signature pages thereto	8-K	001-35312	May 1, 2024	10.1
10.66	Placement Agency Agreement dated as of April 26, 2024, by and between Nuwellis, Inc. and Roth Capital Partners, LLC	8-K	001-35312	May 1, 2024	1.1
10.67	First Amendment to Supply and Collaboration Agreement dated as of May 31, 2024 by and between the Company and DaVita Inc.	8-K	001-35312	June 6, 2024	10.1
10.68	Form of Securities Purchase Agreement	8-K	001-35312	July 25, 2024	10.2
10.69	Placement Agency Agreement dated July 24, 2024 between Nuwellis, Inc. and Roth Capital Partners LLC	8-K	001-35312	July 25, 2024	10.1
10.70	Termination Agreement to the Supply and Collaboration Agreement, dated August 21, 2024	8-K	001-35312	August 22, 2024	10.1
10.71	Placement Agency Agreement dated as of August 23, 2024, by and between Nuwellis, Inc., and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	August 26, 2024	10.1
10.72	Form of Securities Purchase Agreement	8-K	001-35312	August 26, 2024	10.2
10.73	Confidential Settlement Agreement & Release with SeaStar Medical Holding Corporation, dated October 20, 2024	8-K	001-35312	October 23, 2024	10.1
10.74	Form of Warrant Inducement Offer Letter	8-K	001-35312	November 7, 2024	10.1
10.75	Separation and Release Agreement between the Company and Nestor Jaramillo, Jr., dated February 23, 2025	8-K	001-35312	February 24, 2025	10.1

10.76	Letter Agreement between the Company and John L. Erb, dated as of February 18, 2025	8-K	001-35312	February 24, 2025	10.2
10.77**	Supply & Quality Agreement between the Company and Kluge Design, LLC dated as of May 9, 2025	8-K	001-35312	May 12, 2025	10.1
10.78	Securities Exchange Agreement, between the Company and John L. Erb, dated June 9, 2025	8-K	001-35312	June 9, 2025	10.1
10.79	Executive Employment Agreement between the Company and John L. Erb	8-K	001-35312	July 2, 2025	10.1
10.80	At The Market Offering Agreement, dated as of September 3, 2025, by and between the Company and Ladenburg Thalmann & Co. Inc.	8-K	001-35312	September 3, 2025	1.1
10.81	Form of Securities Purchase Agreement, dated as of January 29, 2026, by and among the Company and the Purchaser identified on the signature page thereto	8-K	001-35312	January 30, 2026	10.1
10.82	Placement Agency Agreement, dated as of January 29, 2026, by and between the Company and the Placement Agent	8-K	001-35312	January 30, 2026	10.2
10.83	Form of Registration Rights Agreement, dated as of January 29, 2026, by and among the Company and the Purchaser identified on the signature page thereto.	8-K	001-35312	January 30, 2026	10.3
10.84	Form of Warrant Inducement Offer Letter	8-K	001-35312	January 30, 2026	10.4
10.85	Securities Purchase Agreement, dated January 29, 2026, by and among the Company, Rendiatech and the sellers named therein.	8-K	001-35312	January 30, 2026	10.5
10.86	Offer Letter, by and between Nuwellis, Inc. and Carisa Schultz, effective February 2, 2026	8-K	001-35312	January 30, 2026	10.6
10.87	Collaboration Agreement, dated September 8, 2025, between the Company and Koronis Biomedical Corporation (KBT)				X
19	Nuwellis, Inc. Insider Trading Policy	10-K	001-35312	March 11, 2025	19
21	List of Subsidiaries				X
23.1	Consent of Baker Tilly US, LLP				X

24	Power of Attorney (included on signature page)						X
31.1	Section 302 Certification—CEO						X
31.2	Section 302 Certification—CFO						X
32.1*	Section 906 Certification—CEO						X
32.2*	Section 906 Certification — CFO						X
97	Policy for the Recovery of Erroneously Awarded Compensation	10-K	001-35312	March 11, 2024		97	
101.INS	Inline XBRL Instance Document						X
101.SCH	Inline XBRL Taxonomy Extension Schema Document						X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document						X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document						X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document						X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document						X
104	Cover Page Interactive Data File (formatted as Inline XBRL contained in Exhibit 101)						X

† Indicates management compensatory plan, contract or arrangement.

* 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.

** Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request. Certain portions of the Supply & Quality Agreement that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. A copy of the unredacted Supply & Quality Agreement will be furnished to the SEC upon request.

Item 16. Form 10-K Summary

None

SIGNATURES

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

Date: March 11, 2026

NUWELLIS, INC.

By: /s/ JOHN L. ERB

John L. Erb

President, Chief Executive Officer and Chairman of the Board

POWER OF ATTORNEY

Each individual person whose signature appears below hereby appoints John L. Erb and Carisa Schultz 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JOHN L. ERB</u> John L. Erb	President, Chief Executive Officer and Chairman of the Board (principal executive officer)	March 11, 2026
<u>/s/ CARISA SCHULTZ</u> Carisa Schultz	Chief Financial Officer (principal financial and accounting officer)	March 11, 2026
<u>Katharyn Field</u>	Director	March 11, 2026
<u>Mika Grasso</u>	Director	March 11, 2026
<u>/s/ GREGORY D. WALLER</u> Gregory D. Waller	Director	March 11, 2026
<u>/s/ ARCHELLE GEORGIOU, M.D.</u> Archelle Georgiou, M.D.	Director	March 11, 2026
<u>/s/ DAVID MCDONALD</u> David McDonald	Director	March 11, 2026
<u>/s/ MARTY EMERSON</u> Marty Emerson	Director	March 11, 2026

