Risk Factors Comparison 2024-03-11 to 2023-03-03 Form: 10-K

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Our business faces many risks. We believe the risks described below are the material risks we face. However, the risks described below may not be the only risks we face. Additional unknown risks or risks that we currently consider immaterial may also impair our business operations. If any of the events or circumstances described below actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our shares of common stock could decline significantly. Investors should consider the specific risk factors discussed below, together with the " Cautionary Note Regarding Forward- Looking Statements " and the other information contained in this Annual Report on Form 10- K and the other documents that we will file from time to time with the SEC. Risks Related to Our Business We have limited history of operations and limited experience in sales and marketing, and we might be unsuccessful in increasing our sales and cannot assure you that we will ever generate substantial revenue or be profitable. Prior to our acquisition of the Aquadex Business in August 2016, we did not have a product approved for commercial sale and focused our resources on developing and manufacturing our C- Pulse System. On September 29, 2016, we announced a strategic refocus of our strategy that included halting all clinical evaluations of the C- Pulse System to fully focus our resources on commercializing our Aquadex System, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives. In addition, our business strategy depends in part on our ability to grow our business by establishing an effective sales force and selling our products to hospitals and other healthcare facilities while controlling costs. In addition to heart failure, we have expanded our commercialization efforts into critical care and post- cardiac surgery. In February 2020, we received 510 (k) clearance of the Aquadex SmartFlow system to include pediatric patients who weigh 20kg or more. With this 510 (k) clearance, we have expanded our commercialization efforts into pediatrics. We have limited prior experience with respect to sales or marketing of the Aquadex System across heart failure, critical care, post- cardiac surgery and pediatrics. If we are unsuccessful at marketing and selling our Aquadex System, our operations and potential revenues will be materially adversely affected. We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near- term. We are an emerging company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of $ ~~14~~ **20** . ~~5~~ **2** million **as of** ~~and $ 19. 6 million for the years ended~~ December 31, ~~2022~~ **2023** ~~and 2021, respectively~~ . As of December 31, ~~2022~~ **2023** , our accumulated deficit was $ ~~267~~ **287** . ~~4~~ **6** million. Prior to August 2016, we did not have any products approved for commercialization, generated only limited revenue from our clinical studies and had significant operating losses as we incurred costs associated with the conduct of clinical studies and our research and development programs for our C- Pulse System. We became a revenue- generating company only after acquiring the Aquadex Business from a subsidiary of Baxter in August 2016. We expect to incur additional losses in the near- term as we grow the Aquadex Business, including investments in expanding our sales and marketing capabilities, manufacturing components, and complying with the requirements related to being a U. S. public company listed on Nasdaq. To become and remain profitable, we must succeed in expanding the adoption and market acceptance of the Aquadex System. This will require us to succeed in a range of challenging activities, including training personnel at hospitals and effectively and efficiently manufacturing, marketing and distributing the Aquadex System and related components. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it. We ~~believe that we~~ will need to raise additional capital to fund our operations through the end of fiscal year 2024. If additional capital is not available, we will have to delay, reduce, or cease operations. We believe that we **have sufficient capital to fund our operations through May 31, 2024. We** will need to raise additional capital to fund our operations through the end of fiscal year 2024 ~~; however, there can be no assurance of this~~ . Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, the risk that we may not be able to continue as a going concern may make it more difficult to obtain necessary additional funding on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, require us to use our cash to make payments under such indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions. If we are unable to secure additional funding, our development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations **. If we do not comply with certain tax regulations, including VAT, and similar regulations, we may be subject to additional taxes, customs duties, interest, and penalties in material amounts, which could materially harm our financial condition and operating results. As a result of supplying our business customers in the European Union, we are subject to the Value Added Tax, or VAT, which is typically applied to all goods and services purchased and sold throughout Europe. In 2023, we discovered that our VAT returns from 2017 to 2021 were overdue for filing in Germany. While we do not believe our current exposure is material, we are unable to calculate any interest or penalties that may be assessed. Our tax advisors are working directly with the German tax authorities to determine the value of our exposure. It is possible that we could face VAT audits in the future and that our liability for these taxes could exceed our estimates if non- U. S. tax authorities assert that we are obligated to collect additional tax amounts from our customers and remit those taxes to those authorities. Such an audit**

could be expensive and time- consuming and result in substantial management distraction. If the matter were to be resolved in a manner adverse to us, it could have a material adverse effect on our results of operations and financial condition. Additionally, we could be subject to interest and penalties for any assessment of taxes that could be deemed overdue. Changes in or the improper application of VAT may negatively impact our operating results. Fluctuations in tax rates and duties, changes in tax legislation or regulation or adverse outcomes of these examinations could have a material adverse effect on our results of operations, financial condition, and cash flows. We have identified a material weakness in connection with our internal control over financial reporting which, if not remediated, could adversely affect our business, reputation and stock price. We review and update our internal controls, disclosure controls and procedures, and corporate governance policies as our Company continues to evolve. In addition, we are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (" SOX ") and management is required to report annually on our internal control over financial reporting. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of SOX until the date we are no longer a " smaller reporting company " as defined by applicable SEC rules. Our management' s evaluation of the effectiveness of our internal controls over financial reporting as of December 31, 2023, concluded that our controls were not effective, due to material weaknesses resulting from insufficient headcount to fully ensure adequate segregation of duties relating to the accounting and financial reporting function and the information technology function. Additionally, the company did not prepare and retain contemporaneous documentation to evidence the implementation and operation of controls, including controls related to the review of balance sheet reconciliations, the preparation and recording of journal entries, the review of period end financial reporting checklists and controls over user access. A material weakness is a deficiency or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company' s interim or annual condensed consolidated financial statements will not be prevented or detected on a timely basis. Subject to limitations on liquidity that may prevent or delay additional hirings, the Company is planning to take steps to remediate these material weaknesses as soon as possible. We can give no assurance that these measures will remediate the material weakness in internal control, or that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that may lead to restatements of our financial statements or cause us to fail to meet our reporting obligations. Any such failure could also lead to reputational damage and a decrease in the market price of our stock . Our near- term prospects are highly dependent on revenues from a single product, the Aquadex System. We face significant challenges in expanding market acceptance of the Aquadex System, which could adversely affect our potential sales. Our near- term prospects are highly dependent on revenues from a single product, the Aquadex System, and we have no other commercial products at this time. The established market or customer base for our Aquadex System is limited and our success depends on our ability to increase adoption and utilization of the Aquadex System. Acceptance of our product in the marketplace by health care providers is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by us to inform health care providers of the benefits of using the Aquadex System and to provide further training on its use. We may not be able to build key relationships with health care providers to drive further sales in the United States or sell the Aquadex System outside the United States. Product orders may be cancelled, patients or customers currently using our products may cease to do so and patients or customers expected to begin using our products may not. In addition, market acceptance of the Aquadex System may require that we make enhancements to the system or its components. We cannot be sure that we will be able to successfully develop such enhancements, or that if developed they will be viewed favorable by the market. Our ability to achieve acceptance of our Aquadex System depends on our ability to demonstrate the safety, efficacy, ease- of- use and cost- effectiveness of the system. We may not be able to expand the adoption and market acceptance of the Aquadex System to both the inpatient and outpatient markets and our potential sales could be harmed. We depend on a limited number of customers, the loss of which, or failure of which to order our products in a particular period, could cause our revenues to decline. Our ten largest customers represented 50. 4 % and ~~51~~ **50** . 4 % of our revenues in the ~~years~~ **twelve months** ended December 31, **2023, and** 2022 ~~and 2021~~ , respectively, with our largest customer representing **13. 9 % and** 12. 5 ~~% and 12. 3~~ %, respectively, of our revenues during such periods **. Customer ordering patterns may vary significantly from quarter** . Customer ordering patterns may vary significantly from quarter to quarter, or customers may discontinue providing therapies using our products. If one of our largest customers reduced its purchases in a fiscal period, our revenues for that period may be materially adversely affected. Further, if one of our largest customers discontinued the use of our products, our revenues may be materially adversely affected. We have limited commercial manufacturing experience and could experience difficulty in producing commercial volumes of the Aquadex System and related components or may need to depend on third parties for manufacturing. We have limited experience in commercial manufacturing of the Aquadex System. Following the acquisition of the Aquadex Business in 2016, we began manufacturing Aquadex FlexFlow ® consoles and blood circuits in- house in the fourth quarter of 2017 and Aquadex FlexFlow ® catheters in- house in the third quarter of 2018. We have manufactured the Aquadex SmartFlow ® console since its development in 2019. However, because we have limited prior commercial manufacturing experience, we may incur manufacturing inefficiencies, delays, or interruptions. We may not be able to achieve low- cost manufacturing capabilities and processes that will enable us to manufacture the Aquadex System or related components in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design and production standards required to market our products successfully. If we experience difficulties with our manufacturing operations, we may experience delays in providing products and services to our customers, and our business could be harmed. We depend upon third- party suppliers, including

single- source suppliers, making us vulnerable to supply problems and price fluctuations. We will rely on third- party suppliers, including single- source suppliers, to provide us with certain components of the Aquadex System. We have no long- term contracts with the majority of our third- party suppliers that guarantee volume or the continuation of payment terms. We depend on our suppliers to provide us with materials in a timely manner that meet our quality, quantity and cost requirements. The forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. If we do not increase our sales volumes, which drive our demand for our suppliers' products, we may not procure volumes sufficient to receive favorable pricing, which could impact our gross margins if we are unable to pass along price differences to our customers. Recent global economic cost inflation trends could unfavorably impact pricing from our suppliers, which could impact our gross margins if we are unable to pass along price differences to our customers. Our failure to obtain required components or subassemblies when needed and at a reasonable cost would adversely affect our business. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. Any difficulties in locating and hiring third- party suppliers, or in the ability of third- party suppliers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business. The COVID- 19 pandemic and other public health threats or outbreaks of communicable diseases could have a material adverse effect on our operations and overall financial performance. ~~During 2020 and 2021, we faced challenging social and economic conditions caused by the outbreak of the novel strain of coronavirus, SARS- CoV- 2, and the resulting COVID- 19 pandemic. The rapidly evolving COVID- 19 pandemic disrupted our operations and forced us to implement changes to keep our customers, their patients, and our employees safe. These changes included restrictions on hospital access imposed on our field employees by customers working on the front lines of COVID- 19 and managing the spread of the virus, changes to employee work practices by requiring employees to work remotely, and increased protocols to ensure the safety of those employees that remained on site. The ongoing impact of the COVID- 19 pandemic on our operational and financial performance will depend on certain future developments, including the extent and duration of future outbreaks, the ongoing impact on our customers and hospital access restrictions imposed on our field employees, and effect on our vendors, all of which remain uncertain and cannot be predicted. We may experience curtailed customer demand or constrained supply that could materially adversely impact our business, results of operations and overall financial performance in future periods. Specifically, we may again experience negative impacts from changes in how we conduct business due to the COVID- 19 pandemic, including but not limited to restrictions on travel and in- person meetings, production delays, warehouses and staffing disruptions and shortages, decreases or delays in customer demand and spending, and difficulties or changes to our sales process and customer support.~~ Several hospitals in the U. S. included the Aquadex System in their treatment protocol for fluid management of COVID- 19, especially when dialysis equipment and staff are limited. However, we also experienced changes to our sales practices due to restrictions on hospital access and believe that such restrictions negatively affected revenue in other areas. In addition, the disruption created by COVID- 19 created significant uncertainty about our ability to access the capital markets in future periods. **The ongoing impact of the COVID- 19 outbreak on our operational and financial performance has diminished, but we may still experience downstream effects that will depend on certain future developments, including the ongoing impact on our customers, hospital capital budget constraints, nursing staff shortages, hospital access restrictions imposed on our field employees, and effects on our vendors, all of which remain uncertain and cannot be predicted.** As of the filing date of this Annual Report on Form 10- K, the extent to which the COVID- 19 pandemic may continue to impact our financial condition or results of operations or guidance is uncertain and cannot be reasonably estimated but could be material and last for an extended period of time. The effect of the COVID- 19 pandemic may not be fully reflected in our results of operations and overall financial performance until future periods. The COVID- 19 pandemic and accompanying market volatility, uncertainty and economic disruption also have the effect of heightening many of the other risks described herein ~~. We have been negatively impacted by the prioritization of COVID- 19 patients in hospitals. As a result of the rise in COVID- 19 cases due to the Omicron variant, in 2022 hospitals were prioritizing and allocating beds and other resources for COVID- 19 patients. In this regard, emergencies for patients with heart failure, unrelated to COVID- 19, decreased and there was less emergency usage of the Aquadex System. The impact of the Omicron variant resulted in a decrease in revenues for the fourth fiscal quarter of 2021 and had continuing effects into early 2022~~ . If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute the Aquadex System effectively and our sales will suffer. Our strategy requires us to provide a significant amount of customer service, maintenance, and other technical service to our customers. To provide these services, we have begun, and will need to continue, to develop a network of distribution and a staff of employees and independent contractors in each of the areas in which we intend to operate. We cannot assure that we will be able to organize and manage this network on a cost- effective basis. If we cannot effectively organize and manage this network, then it may be difficult for us to distribute our products and to provide competitive service and support to our customers, in which case customers may be unable, or decide not, to order our products and our sales will suffer. We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results. Competition from medical device companies and medical device divisions of health care companies, pharmaceutical companies and gene- and cell- based therapies is intense and expected to increase. The vast majority of patients with fluid overload receive pharmacological treatment (diuretics) as a standard of care. There are no direct competitors for the Aquadex System in heart failure or critical care in the U. S., other than diuretics. Other systems, such as Baxter' s Prismaflex, a filter- based device that is approved for continuous renal replacement therapy for patients weighing 20kg or more with acute renal failure and / or fluid overload. In pediatrics, the ~~Carpediem~~ **Carpe diem** system distributed by Medtronic is indicated for use in acute kidney injury or fluid overloaded patients requiring hemodialysis or hemofiltration therapy, and Baxter' s HF20 Set is authorized under an Emergency Use Authorization to deliver CRRT to treat patients of low weight (8- 20 kg) in an acute care environment during the COVID-

19 pandemic. Our ability to compete effectively depends upon our ability to demonstrate the advantages of ultrafiltration as compared to diuretics, a pharmacological treatment that is currently the standard of care. In addition, we need to distinguish Aquadex System from the indirect competition of other devices that can also be used to conduct ultrafiltration. Significant additional governmental regulation could subject us to unanticipated delays which would adversely affect our sales. Our business strategy depends in part on our ability to expand the use of the Aquadex System in the market as quickly as possible. To achieve expanded market use of the Aquadex System, we may develop additional enhancements to the system or its components. Depending on their nature, such enhancements may be subject to review by the FDA and regulatory authorities outside of the United States under the applicable regulations. Any regulatory delay in our ability to implement enhancements to the Aquadex System or its components could have an adverse effect on our potential sales. Health care laws in the United States and other countries are subject to ongoing changes, including changes to the amount of reimbursement for hospital services. Additional laws and regulations, or changes to existing laws and regulations that are applicable to our business may be enacted or promulgated, and the interpretation, application or enforcement of the existing laws and regulations may change. Legislative proposals can substantially change the way health care is financed by both governmental and private insurers and may negatively impact payment rates for our system. We cannot predict the nature of any future laws, regulations, interpretations, applications or enforcements or the specific effects any of these might have on our business. However, in the United States and international markets, we expect that both government and third- party payers will continue to attempt to contain or reduce the costs of health care by challenging the prices charged, or deny coverage, for health care products and services. Any future laws, regulations, interpretations, applications or enforcement could delay or prevent regulatory approval or clearance of our Aquadex System and our ability to market our Aquadex System. Moreover, changes that result in our failure to comply with the requirements of applicable laws and regulations could result in the types of enforcement actions by the FDA and / or other agencies as described above, all of which could impair our ability to have manufactured and to sell the affected products. In the United States, the products included in the Aquadex System are purchased primarily by customers, such as hospitals or other health care providers. Customers bill various third- party payers for covered therapies involving the Aquadex System provided to patients. These payers, which include federal health care programs (e. g., Medicare and Medicaid), state health care programs, private health insurance companies and managed care organizations, then reimburse our customers based on established payment formulas that consider part or all of the cost associated with these devices and the related procedures performed. While the agency responsible for administering the Medicare program, the Centers for Medicare and Medicaid Services, has not issued a favorable national coverage determination under its Investigational Device Exception Studies Program for ultrafiltration using the Aquadex System, a number of private insurers have approved reimbursement for the products included in the Aquadex System for specific indications and points of service. In addition, patients and providers may seek insurance coverage on a case- by- case basis. On January 1, 2022, a new and dedicated Category III ~~Current Procedural Terminology (~~ CPT ~~)~~ code, 0692T, became effective for Therapeutic Ultrafiltration. Healthcare providers can utilize this code when using Aquadex to deliver ultrafiltration to adult and pediatric patients (≥ 20kg). The approved temporary Therapeutic Ultrafiltration Category III CPT code will be in effect for at least five years and provides additional reimbursement for ultrafiltration administered in the outpatient setting. Product defects, resulting in lawsuits for product liability, could harm our business, results of operations and financial condition. The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of a product or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to a product (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall of our Aquadex System or any related components could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals. We may be held liable if any product we develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. The safety studies we must perform, and the regulatory approvals required to commercialize our products will not protect us from any such liability. We carry product liability insurance with a $ 6. 0 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any approved product. If such insurance is insufficient to protect us, our business, results of operations and financial condition will be harmed. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. Even if a product liability claim against us is without merit or if we are not found liable for any damages, a product liability claim could result in decreased interest in our registry studies, decreased demand for our system, if approved for commercialization, injury to our reputation, diversion of management' s attention from operating our business, withdrawal of study participants, significant costs of related litigation, loss of revenue or the inability to commercialize our products. We may face significant risks associated with international operations, which could have a material adverse effect on our business, financial condition and results of operations. We market our products globally. Our international operations are subject to a number of risks, including the following: fluctuations in exchange rates of the United States dollar could adversely affect our results of operations, we may face difficulties in enforcing and collecting accounts receivable under some countries' legal systems, have our products serviced or conduct other operations, political instability could disrupt our operations, some governments and customers may have longer payment cycles, with resulting adverse effects on our cash flow, and some countries could impose additional taxes or restrict the import of our products. In addition, regulations in individual countries or regions may restrict our ability to sell our products. Most countries, including the countries in the EU, require approval or registration to import and / or sell our products in the country. The EU ~~Medical Device~~

~~Regulation~~ **MDR was published in May** 2017 **. There** ~~/ 745 (MDR)~~ was **a** ~~adopted in April 2017. The MDR replaces the~~ **three - year transition period for companies to comply with the** ~~existing Medical Device Directives (MDD 93 / 42 / EEC and MDD 90 / 385 / EEC). The~~ new MDR ~~went into effect~~ **requirements, until May 2020. Due to the COVID, the date was extended to May 2021. To ensure a high level of public health protection and avoidance of device shortage,** on **March 20 2023, Regulation (EU) 2023 / 607 amended the MDR as regards the transitional provisions from** May 26, ~~2021~~ **2024 further based on the different device classifications** , **provided certain criteria are met. Our legacy devices, the Aquadex SmartFlow system, including the console** and ~~new CE Mark product must comply with new~~ **blood circuit, is considered non-implantable, class IIb device. The EU** MDR ~~after this date. As of~~ **transition period has been extended from** May 26, ~~2021~~ **2024 to December 31** , ~~companies that~~ **2028. To qualify for the EU MDR transition extension, Nuwellis must • apply for MDR certification with an MDR Notified Body by 26 May 2024 and before their MDD certificate expires, and •** have ~~devices on~~ **a contract in place with an MDR Notified Body before 26 September 2024. We are in** the **process of entering into MDR certification contract with our Notify Body which will allow Nuwellis to** market ~~with~~ **Aquadex SmartFlow ® through Dec 31st, 2028. Nuwellis intends to complete MDR certification and** CE Mark under ~~MDD 93 / 42 / EEC or MDD 90 / 385 / EEC must meet the transitional provisions of the new~~ MDR ~~. Devices lawfully placed on the market under MDD 93 / 42 / EEC or MDD 90 / 385 / EEC before May 26, 2021, may continue to be made available on the market until May 27, 2024, provided the CE Mark was issued~~ prior to ~~this date, the manufacturer continues to comply with either one of the directives, and that no significant changes are made in the design and intended purpose of the applicable medical device. By May 27, 2025, all medical devices entering the EU will need to have a new CE Mark under the MDR, even if they~~ **the extension deadline of Dec 31st** ~~have been on the market previously under the MDD / AIMDD. Manufacturers are required to update their technical documentation and processes to meet the new requirements. Nuwellis ™ received the CE Mark for Aquadex SmartFlow ® on January 13~~ , ~~2020~~ **2028** ~~. Nuwellis received the renewal certificate to include the 24- Hour blood circuit September 3rd, 2021. Our CE certificate for Aquadex SmartFlow ® is under MDD / 93 / 42 EEC and is valid through May 26, 2024 which allow us to sell Aquadex SmartFlow ® System into EU and satisfy future distribution demand~~ . Any one or more of these factors associated with international operations could increase our costs, reduce our revenues, or disrupt our operations, which could have a material adverse effect on our business, financial condition, and results of operations. If we are not able to maintain sufficient quality controls, then the approval or clearance of our products by the EU, the FDA or other relevant authorities could be withdrawn, delayed or denied and our sales will suffer. Approval or clearance of our products could be withdrawn, delayed, or denied by the EU, the FDA and the relevant authorities of other countries if our manufacturing facilities do not comply with their respective manufacturing requirements. The EU imposes requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure to comply with these requirements could prevent us from marketing our products in the European **Union** Community. The FDA also imposes requirements through quality system requirements, or QSR, regulations, which include requirements for good manufacturing practices, or GMP. Failure to comply with these requirements could prevent us from obtaining FDA approval of our products and from marketing such products in the United States. Our manufacturing facilities have not been inspected and certified by a ~~worldwide testing and certification agency (also referred to as a notified~~ **Notified** ~~body~~ **Body** ~~) that performs conformity assessments to EU requirements for medical devices. A " notified body " is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections~~ . We cannot be sure that our facilities or the processes we use will comply or continue to comply with their respective requirements on a timely basis or at all, which could delay or prevent obtaining the approvals we need to market our products in the European **Union** Community and the United States. To market our products in the European Community, the United States and other countries, where approved, manufacturers of such products must continue to comply or ensure compliance with the relevant manufacturing requirements. Although we cannot control the manufacturers of our products, if we choose to subcontract manufacturing to a contract manufacturer, we may need to expend time, resources and effort in product manufacturing and quality control to assist with their continued compliance with these requirements. If violations of applicable requirements are noted during periodic inspections of the manufacturing facilities of our manufacturers or we fail to address issues raised by the FDA in these inspections, then we may not be able to continue to market the products manufactured in such facilities and our revenues may be materially adversely affected. If we violate any provisions of the FDC Act or any other statutes or regulations, then we could be subject to enforcement actions by the FDA or other governmental agencies. We face a significant compliance burden under the FDC Act and other applicable statutes and regulations which govern the testing, labeling, storage, record keeping, distribution, sale, marketing, advertising and promotion of our medically approved products. If we violate the FDC Act or other regulatory requirements at any time during or after the product development and / or approval process, we could be subject to enforcement actions by the FDA or other agencies, including: fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of the production of our products, withdrawal of any existing approvals or pre- market clearances of our products, refusal to approve or clear new applications or notices relating to our products, recommendations that we not be allowed to enter into government contracts and criminal prosecution. Any of the above could have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that our products will be safe or that there will not be serious injuries or product malfunctions. Further, we are required under applicable law to report any circumstances relating to our medically approved products that could result in deaths or serious injuries. These circumstances could trigger recalls, class action lawsuits and other events that could cause us to incur expenses and may also limit our ability to generate revenues from such products. We cannot assure you that our products will prove to be safe or that there will not be serious injuries or product malfunctions, which could trigger recalls, class action lawsuits and other events that could cause us to incur significant expenses, limit our ability to market our products and generate revenues from such products or cause us reputational harm. Under the FDC Act, we are required to submit medical device reports, or MDRs, to the

FDA to report device- related deaths, serious injuries and malfunctions of medically approved products that could result in death or serious injury if they were to recur. Depending on their significance, MDRs could trigger events that could cause us to incur expenses and may also limit our ability to generate revenues from such products, such as the following: information contained in the MDRs could trigger FDA regulatory actions such as inspections, recalls and patient / physician notifications; because the reports are publicly available, MDRs could become the basis for private lawsuits, including class actions; and if we fail to submit a required MDR to the FDA, the FDA could take enforcement action against us. If any of these events occur, then we could incur significant expenses and it could become more difficult for us to market and sell our products and to generate revenues from sales. Other countries may impose analogous reporting requirements that could cause us to incur expenses and may also limit our ability to generate revenues from sales of our products. We face significant uncertainty in the industry due to government healthcare reform. The Affordable Care Act, as well as other healthcare reform may have a significant impact on our business. The Affordable Care Act is extremely complex, and, as a result, additional legislation is likely to be considered and enacted over time. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The uncertainties regarding the implementation of the Affordable Care Act, including possible repeal of the Affordable Care Act, ongoing legal challenges, and further judicial interpretations, create unpredictability for the health care industry, which itself constitutes a risk. The Affordable Care Act includes a Hospital Readmission Reduction program and is designed to reduce payments to hospitals with excess heart failure readmissions, among other conditions. The penalty to hospitals can be significant, as much as 3 % of total Medicare reimbursement. We believe the Aquadex System may offer hospitals an economic benefit for using the device on a regular basis for in- patient or out- patient usage to avoid readmissions for heart failure; however, if the Hospital Readmission Reduction program is repealed, hospitals may not be as inclined to take measures to reduce readmissions. In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years, but if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future. Moreover, the Physician Payment Sunshine Act (the " Sunshine Act "), which was enacted as part of the Affordable Care Act, requires applicable medical device companies to track and publicly report, with limited exceptions, all payments and other transfers of value to physicians and teaching hospitals in the U. S. Implementing regulations for these tracking and reporting obligations were finalized in 2013, and companies have been required to track payments made since August 1, 2013. If we fail to comply with the data collection and reporting obligations imposed by the Sunshine Act, we may be subject to substantial civil monetary penalties. We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties. Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute, the Stark law and federal False Claims Act (the " FCA "). These laws may impact, among other things, our sales, marketing and education programs. The federal Anti- Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute' s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti- Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti- Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti- Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. The physician self- referral laws, commonly referred to as the Stark law, is a strict liability statute that generally prohibits physicians from making referrals for the furnishing of any " designated health services, " for which payment may be made under the Medicare or Medicaid programs, to any entity with which the physician (or an immediate family member) has an ownership interest or compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self- referrals, regardless of the source of the payment for the patient' s care. If it is determined that any of the relationships we may have with physicians violate the Stark law or similar statutes, we could become subject to civil and criminal penalties. The imposition of any such penalties could harm our business. The FCA prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the FCA, known as " qui tam " actions, can be brought by any individual on behalf of the government and such individuals, commonly known as " whistleblowers, " may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a FCA action. When an entity is determined to have violated the federal FCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal FCA. We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties,

including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations. Failure to comply with anti- bribery, anti- corruption, and anti- money laundering laws could subject us to penalties and other adverse consequences. We are subject to the Foreign Corrupt Practices Act (" FCPA "), the U. K. Bribery Act and other anti- corruption, anti- bribery and anti- money laundering laws in various jurisdictions both domestic and abroad. The FCPA prohibits any U. S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The U. K. Bribery Act is similar but even broader in scope in that it prohibits bribery of private (non- government) persons as well. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including its international subsidiary, and to devise and maintain an adequate system of internal accounting controls for international operations. Our distribution arrangements outside the U. S. presents some risk under these laws. Our distributors may sell our products to healthcare providers that are owned, controlled or managed by a foreign government and its employees, including healthcare providers may be deemed to be a foreign official under the FCPA. We could be held liable for the actions of our distributors. While we have policies and procedures to address compliance with these laws, we cannot assure you that our distributors will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. Noncompliance with these laws could subject us to investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, adverse media coverage and other consequences. Any investigations, actions or sanctions could adversely affect our business, operating results and financial condition. If we acquire other businesses, products or technologies, we could incur additional impairment charges and will be subject to risks that could hurt our business. We may pursue acquisitions to obtain complementary businesses, products or technologies. Any such acquisition may not produce the revenues, earnings or business synergies that we anticipate, and an acquired business, product or technology might not perform as we expect. Our management could spend a significant amount of time, effort and money in identifying, pursuing and completing the acquisition. If we complete an acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired businesses, products or technologies into our operations. In particular, we may lose the services of key employees and we may make changes in management that impair the acquired business' s relationships with employees, vendors and customers. Additionally, we may acquire development- stage companies that are not yet profitable and which require continued investment, which could decrease our future earnings or increase our futures losses. Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced. As a result of a potential acquisition, we may be required to capitalize a significant amount of intangibles, including goodwill. We would be required review our definite- lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets. In addition, we would be required to evaluate goodwill for impairment annually, or to the extent events or conditions indicate a risk of possible impairment during the interim periods prior to its annual impairment test. In the year ended December 31, 2017, we recognized impairment charges of $ 4. 0 million related to goodwill and intangibles assets from our acquisition of the Aquadex Business. If we were required to recognize impairment charges related to future acquisitions, those charges could decrease our future earnings or increase our future losses. Risks Related to Our Intellectual Property We may not be able to protect our intellectual property rights effectively, which could have an adverse effect on our business, financial condition or results of operations. Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our Aquadex System and related components. On August 5, 2016, upon closing of our acquisition of the Aquadex Business, we entered into a patent license agreement with Baxter pursuant to which we obtained, for no additional consideration, a world- wide license to 49 exclusively licensed and 9 non- exclusively licensed patents used in connection with the Aquadex System to make, have made, use, sell, offer for sale and import, the Aquadex System in the " field of use " as defined in the license. The license is exclusive, with respect to some patents, and non-exclusive, with respect to other patents. Under the patent license agreement, Baxter has agreed to use commercially reasonable efforts to continue maintenance of seven " required maintenance patents, " and we have agreed to reimburse Baxter for all fees, costs, and expenses (internal or external) incurred by Baxter in connection with such continued maintenance. The rights granted to us under the patent license agreement will automatically revert to Baxter in the event we cease operation of the Aquadex Business or we file for, or have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. We estimate that the patents licensed from Baxter will expire **by mid-** ~~between approximately 2023 and~~ 2026. We have ~~thirteen~~ **twenty** pending patent applications. The first application is based on our design for a wearable device designed to assist in maintaining peripheral venous blood flow access in the arm during ultrafiltration treatment. The second application includes multiple potential new features and capabilities relating to help patient fluid balance and to improve usability for healthcare providers. The third application involves a vacuum pump- controlled wearable appliance to increase vein diameter and venous flow for peripheral ultrafiltration. The fourth application involves plasma and blood volume measurement to guide ultrafiltration therapy. The fifth application involves new features for ultrafiltration for the benefit of pediatric patients. The sixth application involves a dual- lumen ultrafiltration catheter for improved peripheral access. The seventh application involves a combination of diagnostic parameters to guide ultrafiltration therapy. The eighth application involves a multi- stage cytokine filtration system. The ninth application involves a system for ensuring that peripheral venous flow is maintained during ultrafiltration and other CKRT modalities. The tenth application enables an ultrafiltration system to provide better patient fluid

balance. **We have filed 10 patent applications related to our dedicated pediatric device in development. These resulted in 2 issued patents, 1 abandoned application, and 7 pending patent applications. The first issued patent involves a mechanical design for the therapy bags to allow easy load / unload by the user. The second issued patent involves transport mode operation on battery power, enabling patient mobility. Other 7 pending patent applications involve an extracorporeal blood filtration machine that includes flexible source line connection, open vs. closed loop fluid collection controls, a self- emptying bag, improved density measurement techniques, algorithm to ensure reliable auto clamp safety engagement, a blood leak detector that can detect hemolyzed blood, and mechanical cartridge design to ease manufacturing assembly and user setup.** In addition, as of ~~February 24~~ **January 30** , ~~2023~~ **2024** , we owned ~~38~~ **16** issued patents and ~~one~~ **14** pending patent applications in the United States and in foreign jurisdictions related to our C- Pulse System and had one pending application for neuromodulation. We estimate that most of our currently issued U. S. patents will expire by 2027. Given the strategic refocus away from the C- Pulse System and towards the Aquadex System, we have chosen to limit the maintenance of issued C- Pulse System related patents to those innovations that are of the highest value. Further, we have elected to emphasize a few of the most critical jurisdictions rather than maintain the earlier approach that involved multiple countries. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any financial return. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to obtain commercial benefits from them. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management' s attention from our business. Intellectual property litigation could be costly and disruptive to us. In recent years, there has been significant litigation involving intellectual property rights in the medical device industry. From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in our business. Any claims, with or without merit, could be time- consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following: • halt use of our Aquadex System; • attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or • redesign our system. In the event a claim against us were successful and we could not obtain a license to the relevant technology on acceptable terms or license a substitute technology or redesign our system to avoid infringement, our business, results of operations and financial condition would be significantly harmed. If we were unable to protect the confidentiality of our proprietary information and know- how, the value of our technology and system could be adversely affected. In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know- how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products. Our commercial success depends, in part, on our ability to increase adoption of the Aquadex System without infringing the patents and other proprietary rights of third parties. As our industry expands and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our system and technologies of which we are not aware or that we must challenge to continue our operations as currently contemplated. Our system may infringe or may be alleged to infringe these patents. In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed, and may in the future file, patent applications covering our system or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to ours, we may have to participate in an interference or derivation proceeding declared by the U. S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U. S. patent position with respect to such inventions. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in our industry, we employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. In the ordinary course of our business, we may collect and store sensitive data, including legally protected health information, personally identifiable

information, intellectual property and proprietary business information owned or controlled by ourselves or others. At times we may have access to limited amounts of protected health information as part of other healthcare providers' provision of treatment to patients with our medical devices. We manage and maintain our applications and data utilizing on- site systems. These applications and data encompass a wide variety of business- critical information including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information, including: loss of access risk; inappropriate disclosure risk; inappropriate modification risk; and the risk of our being unable to adequately monitor our controls over the first three risks. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws and regulations that protect the privacy of personal information and regulatory penalties. To the extent that we may engage in activities regulated by the Health Insurance Portability and Accountability Act ~~(HIPAA)~~ and the Health Information Technology for Clinical and Economic Health Act ~~(HITECH)~~ we may have additional regulatory and reporting obligations. We are also subject to the General Data Protection Regulation (EU) 2016 / 679 due to our business in the EU. Although we believe we have implemented security measures, there is no guarantee we can protect our systems and data from unauthorized access, loss or dissemination that could also disrupt our operations, including our ability to conduct our analyses, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business. In addition, the interpretation and application of consumer, health- related, and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government- imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Risks Related to Our Common Stock ~~Our failure~~ **Nasdaq may delist our common stock from its exchange which could limit your ability** to ~~meet~~ **make transactions in our securities and subject us to additional trading restrictions. On December 7, 2023, we received a Notice informing us that because** the **closing bid price for our common stock listed on Nasdaq was below $ 1. 00 for 30 consecutive trading days, we were not in compliance with the Minimum Bid Price Rule for** continued listing ~~requirements of the NASDAQ Capital Market could result in a delisting of our common stock. Our common stock is listed~~ on the Nasdaq Capital Market ~~under the symbol " NUWE "~~ **, as set forth in Nasdaq Marketplace Rule 5550 (a) (2)** . In ~~order~~ **accordance with Nasdaq Marketplace Rule 5810 (c) (3) (A), the Company has a period of 180 calendar days from December 7, 2023, or until June 4, 2024,** to ~~maintain~~ **regain compliance with the Minimum Bid Price Requirement. If at any time before June 4, 2024, the closing bid price of the Company' s common stock closes at or above $ 1. 00 per share for a minimum of 10 consecutive trading days (which number days may be extended by Nasdaq), Nasdaq will provide written notification** that **the Company has achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved. The Notice also disclosed that in the event the Company does not regain compliance with the Minimum Bid Price Rule by June 4, 2024, the Company may be eligible for additional time. To qualify for additional time, the Company would be required to meet the continued** listing ~~, we must satisfy minimum financial~~ **requirement for market value of publicly held shares** and **all** other ~~requirements including~~ **initial listing standards for Nasdaq** , **with** ~~without limitation,~~ the **exception of** ~~minimum stockholders' equity requirement and~~ the ~~minimum~~ bid price requirement **, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that the Company' s securities will be subject to delisting. The Company intends to continue actively monitoring the closing bid price for the Company' s common stock between now and June 4, 2024, and it will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement. If the Company does not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company' s common stock will be subject to delisting. The Company would then be entitled to appeal that determination to a Nasdaq hearings panel** . There can be no ~~assurances~~ **assurance** that ~~we~~ **the Company** will ~~be successful in maintaining, or if we fall out of compliance, in regaining~~ --- **regain** compliance with the ~~continued~~ **Minimum Bid Price Requirement during the 180- day compliance period, secure a second period of 180 calendar days to regain compliance, or maintain compliance with the other Nasdaq** listing requirements ~~and maintaining the listing of our common stock on the Nasdaq Capital Market. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities and we would incur additional costs under requirements of state " blue sky " laws in connection with any sales of our securities. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities~~ . If ~~our common stock is delisted by Nasdaq, the price of our common stock may decline and our common stock may be eligible to trade on the OTC Bulletin Board, another over- the- counter quotation system, or on the pink sheets, which would negatively affect the liquidity of our common stock and an~~

~~investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. In addition, if~~ our common stock is delisted from ~~the~~ Nasdaq **, our ability to raise** ~~Capital~~ **capital** ~~Market~~ **through public offerings of our securities** and ~~the trading price remains below $ 5~~ **to finance our operations could be adversely affected** . ~~00 per share, trading~~ **We also believe that delisting would likely result in decreased liquidity and / or increased volatility** in our common stock ~~might also become subject~~ **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** ~~the~~ **then** ~~requirements~~ **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 ~~certain~~ **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 ~~promulgated under the Exchange Act~~ , ~~which require~~ **possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage for our Company; and a decreased ability to issue** additional ~~disclosure by broker~~ **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** ~~dealers in connection with any trade involving a stock defined as a~~ " 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** ~~any~~ **an** equity security ~~not listed on a national securities exchange or quoted on Nasdaq~~ that has a market price of less than $ 5. 00 per share, subject to ~~certain~~ **specific** ~~exceptions~~ **exemptions** ~~)~~ **. If our common stock is delisted from Nasdaq and it trades on the over- the- counter market at a price of less than $ 5. 00 per share, our common stock would be considered a penny stock. The SEC' s penny stock rules require a broker- dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker- dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker- dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer' s account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker- dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser' s agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers- dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock** . On December 9, 2022, we effected a 1- for- 100 reverse stock split of our outstanding common stock. All share amounts and warrant or option exercise prices contained in this report reflect that adjustment. Additionally, in 2020, the SEC approved a Nasdaq rule change to expedite delisting of securities of companies that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two- year period. Under the new rules, if a company falls out of compliance with the $ 1. 00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any compliance periods and Nasdaq will instead require the issuance of a Staff delisting determination, which is appealable to a hearings panel. Our ability to remain listed on the Nasdaq Capital Market may be negatively impacted by this new Nasdaq rule. We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter. Sales of a substantial number of shares of our common stock by our stockholders in the public market could cause our stock price to fall. The number of shares of common stock issuable upon conversion of our outstanding preferred stock and exercise of outstanding warrants is significant in relation to the number of shares of our common stock currently outstanding. As of ~~February 24~~ **December 31** , 2023, we have warrants to purchase **2, 963,** ~~19~~ **192** ~~, 190~~ shares of common stock outstanding, with exercise prices ranging from $ ~~25~~ **3. 30** to $ ~~89~~ **189** , ~~040~~ **000** with a weighted- average exercise price of $ **30** ~~2, 201~~ . ~~79~~ **86** . As of ~~February 24~~ **December 31** , 2023, there were 127 shares of Series F **Convertible Redeemable** Preferred Stock **, par value $ 0. 0001 per share (the " Series F Convertible Preferred Stock ")** outstanding, convertible into ~~5~~ **125** , ~~080~~ **857** shares of common stock. The certificate of designation for our Series F **Convertible** Preferred Stock contains an anti- dilution provision, which provision requires the lowering of the applicable conversion price, as then in effect, to the purchase price per share of common stock or common stock equivalents issued in the future. If the effective price per share on a common- stock equivalent basis in a future equity offering is lower than the then- current conversion price of the Series F Convertible Preferred Stock, then such conversion price shall be reduced to such lower price and additional shares of common stock will be issuable upon the conversion of the of the Series F Convertible Preferred Stock. To the extent the outstanding shares of Series F Convertible Preferred Stock become exercisable for additional shares of common stock, holders of our common stock will experience further dilution. **As of December 31, 2023, there were 11, 950 shares of Series J Convertible Preferred Stock (as defined below) outstanding, convertible into 295, 792 shares of common stock and 66, 917 Series J Convertible Preferred Stock issuable upon the exercise of 133, 834 warrants issued in the October 2023 Offering (as defined below).** If any security holder determines to sell a substantial number of shares into the

market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock could depress the trading market for our common stock over an extended period of time. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of December 31, ~~2022~~ **2023** , we have outstanding warrants to purchase an aggregate of approximately ~~679~~ **2** , ~~244~~ **963, 192** shares of our common stock, and options to purchase an aggregate of approximately ~~10~~ **110** , ~~485~~ **916** shares of our common stock, which, if exercised, may further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market. The rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of our outstanding preferred stock and stock that may be issued in the future. Our board of directors has authority, without further stockholder approval, to issue additional shares of preferred stock with such rights, preferences and privileges as our board may determine. These rights, preferences and privileges may include dividend rights, conversion rights, voting rights and liquidation rights that may be greater than the rights of our common stock. Our board of directors has previously approved, pursuant to this authority, the issuance of preferred stock, and we have 127 shares of Series F **Convertible Preferred Stock outstanding and 11, 950 shares of Series J Convertible** Preferred Stock outstanding as of ~~February 24~~ **December 31** , 2023. Upon liquidation, dissolution or winding- up of the Company, holders of our Series F **Convertible Preferred Stock and Series J Convertible** Preferred Stock have the right to receive, out of the assets, whether capital or surplus, of the Company an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of such preferred stock held by such holder before any distribution or payment shall be made to the holders of our common stock, and, following such payment, such holders are entitled to receive the same amount that a holder of common stock would receive if such preferred stock was fully converted, pari passu with all the holders of common stock. Our board of directors may issue additional series of preferred stock. As a result, the rights of holders of our capital stock will be subject to, and could be adversely affected by, the rights of holders of any stock that may be issued in the future. There may be future sales of our securities or other dilution of our equity, which may adversely affect the market price of our common stock. We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur. We have a large number of authorized but unissued shares of stock, which could negatively impact a potential investor if they purchased our common stock. On December 9, 2022, we effected a 1- for- 100 reverse split of our outstanding common stock. This reverse stock split did not change the par value of our common stock or the number of common or preferred shares authorized by our **Fourth Amended and Restated** Certificate of Incorporation **, as amended (our " Certificate of Incorporation ")** . Because the number of authorized shares of our common stock was not reduced proportionately, the reverse stock split increased our board of directors' ability to issue authorized and unissued shares without further stockholder action. As of ~~February 24~~ **December 31** , 2023 our ~~certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** provides for 100, 000, 000 shares of authorized common stock and 40, 000, 000 shares of authorized preferred stock, 30, 000 of which are designated Series A Junior Participating Preferred Stock, ~~127~~ **18, 000** of which are designated Series F **Convertible** Preferred Stock, **600, 000 of which are designated Series J Convertible Redeemable Preferred Stock** and we have ~~1~~ **5** , ~~206~~ **682** , ~~932~~ **461** shares of common stock outstanding, ~~47~~ **3** , ~~080~~ **495, 757** shares reserved for issuance upon the conversion, exercise or vesting of outstanding preferred stock, warrants and options, **66** ~~and 153~~ , ~~712~~ **917 Series J Convertible Preferred Stock issuable upon the exercise of 133, 834 warrants issued in the October 2023 Offering, and 41, 871** shares of common stock reserved for future grant under the Company' s equity incentive plans. With respect to authorized but unissued and unreserved shares, we could also use such shares to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management. The issuance of additional shares of common stock or securities convertible into common stock may have a dilutive effect on earnings per share and relative voting power and may cause a decline in the trading price of our common stock. We could use the shares that are available for future issuance in dilutive equity financing transactions, or to oppose a hostile takeover attempt or delay or prevent changes in control or changes in or removal of management, including transactions that are favored by a majority of the stockholders or in which the stockholders might otherwise receive a premium for their shares over then- current market prices or benefit in some other manner. A more active, liquid trading market for our common stock may not develop, and the price of our common stock may fluctuate significantly. Historically, the market price of our common stock has fluctuated over a wide range. There has been relatively limited trading volume in the market for our common stock, and a more active, liquid public trading market may not develop or may not be sustained. Limited liquidity in the trading market for our common stock may adversely affect a stockholder' s ability to sell its shares of common stock at the time it wishes to sell them or at a price that it considers acceptable. If a more active, liquid public trading market does not develop we may be limited in our ability to raise capital by selling shares of common stock and our ability to acquire other companies or assets by using shares of our common stock as consideration. In addition, if there is a thin trading market or " float " for our stock, the market price for our common stock may fluctuate significantly more than the stock market as a whole. Without a large float, our common stock would be less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile and it would be harder for a stockholder to liquidate any investment in our common stock. Furthermore, the stock market is subject to significant price and volume fluctuations, and the price of our common stock could fluctuate widely in response to several factors, including: • our quarterly or annual operating results; • changes in our earnings estimates; • investment recommendations by securities analysts following our business or our industry; • additions or departures of key

personnel; • changes in the business, earnings estimates or market perceptions of our competitors; • our failure to achieve operating results consistent with securities analysts' projections; • future announcements concerning us, including our clinical and product development strategy, or our competitors; • regulatory developments, disclosure regarding completed, ongoing or future clinical studies and enforcement actions bearing on advertising, marketing or sales; • acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to manufacture our system; • fluctuations of investor interest in the medical device sector; • changes in industry, general market or economic conditions; and • announcements of legislative or regulatory changes. The stock market has experienced extreme price and volume fluctuations in recent years that have significantly affected the quoted prices of the securities of many companies, including companies in the health care industry. The changes often appear to occur without regard to specific operating performance. The price of our common stock could fluctuate based upon factors that have little or nothing to do with us and these fluctuations could materially reduce our stock price. Our ability to use U. S. net operating loss carryforwards might be limited. As of December 31, ~~2022~~ **2023**, we had U. S. net operating loss (" NOL ") carryforwards of approximately $ ~~198~~ **212** ~~1~~ **2** million for U. S. federal income tax purposes. Approximately $ ~~120~~ **119** ~~1~~ **7** million of NOL carryforwards will expire from 2024 through 2037. Pursuant to the Tax Cuts and Jobs Act of 2017, the NOL carryforwards generated in 2018 through ~~2020~~ **2023** totaling approximately $ ~~78~~ **92** ~~0~~ **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** ~~As of December 31, 2022, the Company~~ **company does** ~~no~~ **not** ~~longer had~~ **have any foreign** tax loss **carryovers** ~~carryforwards in the Commonwealth of Australia due to the dissolution of its Australian subsidiary in November 2020~~. We believe the Company may have experienced additional ownership changes under Section 382 of the Internal Revenue Code in the current and earlier years further limiting the NOL carryforwards that may be utilized. We have not yet completed a formal Section 382 analysis. As a result, prior or future changes in ownership could put limitations on the availability of our NOL carryforwards. In addition, our ability to utilize the current NOL carryforwards might be further limited by future issuances of our common stock. We do not intend to pay cash dividends on our common stock in the foreseeable future. We have never declared or paid any cash dividends on our common stock, and we currently do not anticipate paying any cash dividends in the foreseeable future. We intend to retain any earnings to finance the development and expansion of our products and business. Accordingly, our stockholders will not realize a return on their investments unless the trading price of our common stock appreciates. Provisions in our charter documents and Delaware law may delay or deter a change- in- control transaction or limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Delaware law and certain provisions of our Certificate of Incorporation and bylaws make it harder for a third party to acquire us, even if doing so might be beneficial to our stockholders. These provisions include, among other things: authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent; requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting; prohibiting stockholders from calling a special meeting of stockholders; and requiring at least two- thirds of the voting power of our outstanding stock entitled to vote to amend or repeal **certain provisions of** our Certificate of Incorporation or bylaws. Section 203 of the Delaware General Corporation Law from which we did not elect to opt out, provides that if a holder acquires 15 % or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change in control of us, and they could limit the price that investors might be willing to pay in the future for shares of our common stock. Further, our Certificate of Incorporation establishes that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. We are a " smaller reporting company " under federal securities laws and we cannot be certain whether the reduced reporting requirements applicable to such companies will make our common stock less attractive to investors. We are a " smaller reporting company " under federal securities laws. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than $ 250 million or (ii) our annual revenue was less than $ 100 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700 million. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or be more volatile. Item 1B. Unresolved Staff Comments.