Risk Factors Comparison 2024-03-01 to 2023-03-22 Form: 10-K

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You should carefully consider the following risks and all other information contained in this Annual Report on Form 10- K and our other public filings before making any investment decisions with respect to our securities. If any of the following risks occurs, our business, prospects, reputation, results of operations, or financial condition could be harmed. In that case, the trading price of our securities could decline, and our stockholders could lose all or part of their investment. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of specific factors, including the risks described below and elsewhere in this Annual Report on Form 10- K. Summary of Risk Factors Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, prospects, reputation, results of operations, or financial condition. Such risks include, but are not limited to: • We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability. • Our future capital needs are uncertain. Our operations could be curtailed if we are unable to obtain the required additional funding when needed. The terms of any financings may not be advantageous to us. • We hold an investment portfolio of securities that could experience losses. • ~~Our financial condition and results of operations may be adversely affected by a resurgence of the coronavirus. •~~ We are focused on growing sales of ~~DPNCheck, our test for peripheral neuropathy, and~~ Quell, our wearable device for chronic pain **, and DPNCheck, our test for peripheral neuropathy** . We cannot assure you that we will be successful with these products or future product candidates or product enhancements in our development pipeline. • Our current and future revenue is dependent upon commercial acceptance of our products in the marketplace. If our products are not accepted by prescribers and customers, our operations will be materially and adversely affected. • If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third- party health care payers related to the use of our products **,** other than Quell, their adoption and our future product sales will be materially adversely affected. • The clinical study process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical study results, or the safety profile for such products or products under development. • We rely on third parties to conduct ~~our~~ clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates. • We depend on several single source manufacturers to produce components of our products. Any material adverse changes in our relationships with these manufacturers, or material supply chain delays, could prevent us from delivering products to our customers in a timely manner and may adversely impact our future revenues or costs. • ~~If our manufacturers are unable to supply us with an adequate supply of product components, we could lose customers, our potential future growth could be limited and our business could be harmed. •~~ The success of our business depends upon our ability to advance our pipeline products to commercialization. • Our ability to achieve profitability depends in part on maintaining or increasing our gross margins on product sales which we may not be able to achieve. • If we ~~lose any of our officers or key employees, our management and technical expertise could be weakened significantly. • If we~~ are unable to recruit, hire and retain skilled and experienced personnel, our ability to manage and expand our business will be harmed, which would impair our future revenues and profitability. • Failure to develop or enter into relationships to sell products other than our existing products or enhance our existing products could have an adverse effect on our business prospects. • If we are unable to develop new products or enhance existing products, we may be unable to attract or retain customers. • We currently compete, and may in the future need to compete, against other medical device and consumer companies with greater resources, more established distribution channels and other competitive advantages, and the success of these competitors may harm our ability to generate revenues. • **Cybersecurity incidents,** ~~Security~~ **security** breaches and other disruptions could compromise our information **, hinder our ability to perform essential activities** and expose us to **financial claims and** ~~liability~~ **liabilities** , which could cause our business and reputation to suffer. • If future clinical studies or other articles are published, or physician associations or other organizations announce positions that are unfavorable to our products, our sales efforts and revenues may be negatively affected. • If we expand in foreign markets, we will be affected by new business risks that may adversely impact our financial condition or results of operations. • We are subject to extensive regulation by the FDA and other federal and state regulators which could restrict the sales and marketing of Quell, DPNCheck and ADVANCE, as well as other products for which we may seek FDA clearance or approval, and could cause us to incur significant costs. • If we or our manufacturers fail to comply with the FDA' s quality system regulation, the manufacturing and distribution of our products could be interrupted, and our product sales and operating results could suffer. • We are subject to Federal Trade Commission regulatory oversight. Exercise of this regulatory oversight could lead to an outcome which would constrain our marketing of Quell, cause us to incur significant costs and penalties, and adversely affect our financial results. • Our products may be subject to recalls, even after receiving FDA clearance or approval, which would harm our reputation, business and financial results. • We are subject to federal and state laws prohibiting " kickbacks " and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business. • If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities, damage our reputation and harm our business. • The use of our products could result in product liability claims that could be expensive, damage our

reputation and harm our business. • Our products are complex in design, and defects may not be discovered prior to shipment to customers, which could result in warranty obligations or product liability or other claims, reducing our revenues and increasing our costs and liabilities. • The patent rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would harm our ability to compete in the market. • Other rights and measures we have taken to protect our intellectual property may not be adequate, which would harm our ability to compete in the market. • ~~We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market. •~~ Claims that our products infringe on the proprietary rights of others could adversely affect our ability to sell our products and increase our costs ~~. • We identified a material weakness in our internal control over financial reporting. If our remediation measures are ineffective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to report our financial condition or results of operations accurately or in a timely manner and we may be unable to maintain compliance with applicable stock exchange listing requirements, which may adversely affect investor confidence in us and, as a result, materially and adversely affect our business and the value of our common stock~~ . • Future sales of securities may cause our stock price to decline as a result of the dilution which will occur to existing stockholders. • The trading price of our common stock has been volatile and is likely to be volatile in the future. • We have, in the past, failed to satisfy certain continued listing requirements on **The** Nasdaq **Stock Market LLC (Nasdaq)** and could fail to satisfy those requirements again in the future which could affect the market price of our common stock and liquidity and reduce our ability to raise capital ~~. • Anti- takeover provisions in our organizational documents and Delaware law, and the shareholder rights plan that we adopted in 2007 and updated in 2021, may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management. • We do not intend to pay cash dividends~~ . Risks Related to Our Business We have incurred recurring losses from operations and negative cash flows from operating activities. At December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~203~~ **210** . ~~6~~ **1** million. The extent of our future operating income or losses is highly uncertain, and we cannot assure you that we will be able to achieve or maintain profitability. **Our future capital needs are uncertain. Our operations could be curtailed if we are unable to obtain the required additional funding when needed. The terms of any financing may not be advantageous to us.** We held cash, cash equivalents and investment grade securities of $ ~~21~~ **18** . ~~2~~ **0** million as of December 31, ~~2022~~ **2023** . We believe that these resources, and the cash to be generated from future product sales will be sufficient to meet our projected operating requirements for at least the next twelve months from the day of issuance of the financial statements. However, we may still need to raise additional funds to support our future operating and capital needs. We expect to incur further losses as we grow sales of **our products** ~~DPNCheck and Quell~~ . We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) the effect of supply chain issues on our ability to obtain parts and materials from our suppliers; (c) changes we may make to the business that affect ongoing operating expenses; (d) changes we may make in our business strategy; (e) regulatory developments and inquiries affecting our existing products; (f) changes in our research and development spending plans; and (g) other items affecting our forecasted level of expenditures and use of cash resources. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, asset divestitures, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or to grant licenses on terms that are not favorable to us. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected. We invest our cash resources not required for near- term operations in a portfolio of debt securities ~~which we intend to hold to maturity~~ . These securities are evaluated by independent rating agencies and meet the criteria of " investment grade " securities at the time of purchase. Changes in domestic or world- wide economic conditions, or in the operations of the issuing entities could result in a rating downgrade of the securities or an inability of the issuer to meet its obligation to the Company upon maturity. In this event, the Company would be exposed to loss in value of the security. If the change in economic conditions was so severe as to affect the overall securities market and therefore a significant part of the Company' s portfolio, the loss in value could jeopardize the Company' s ability to adequately fund its operations, its strategic initiatives and achieve its development and commercialization goals. ~~The resurgence of the COVID- 19 coronavirus pandemic, and any future outbreak of contagious diseases, or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our customers, distributors and suppliers to maintain normal business activities. It could also affect the ability of our personnel to perform their normal responsibilities and could result in temporary closures of our facilities. COVID- 19 continues to affect individuals and businesses around the globe.~~ We **are** ~~may experience disruptions that could severely impact our business, including: • restrictions on the conduct of our business imposed by governmental regulators; • diversion or prioritization of healthcare resources away from clinical trials and diagnostic testing using our medical devices by physician clinics, hospitals, home testing services and other healthcare providers; • supply chain disruption, including delays in fulfillment or cancellations of purchase orders by our parts and services suppliers which would hamper our manufacturing capabilities; • limitations on~~

~~employee resources that would otherwise be~~ focused on **growing sales** ~~our business activities, including because~~ of **Quell,** ~~sickness of employees or~~ **our** ~~their families~~ **wearable device** ~~or~~ **for** ~~requirements imposed on employees to avoid contact~~ **chronic pain, and DPNCheck, our test for peripheral neuropathy, and. We cannot assure you that we will be successful** with **these products** ~~large groups of people; • disruption in our~~ **or** ~~distribution channels, including shipping providers and distributors. Our~~ future ~~results of operations could be adversely affected to~~ **product candidates or product enhancements in our development pipeline. Quell was launched in June 2015, and is a wearable neuromodulation device for** the ~~extent that COVID~~ **symptomatic relief and management of chronic pain indications. We are leveraging our core Quell technology into a portfolio of Rx wearable neurotherapeutics. Quell** ~~19 or~~ **Fibromyalgia, the first product in this emerging portfolio, was launched in late 2022 as** ~~any~~ **an aid** ~~other epidemic harms our business or~~ **for reducing** ~~the economy in general either domestically or in any other~~ **the** ~~region~~ **symptoms of fibromyalgia** in **adults** ~~which we do business. The extent to which our operations and financial condition could be harmed will depend on future developments which are uncertain and cannot be predicted~~ with ~~confidence~~ **high pain sensitivity**. **We have recently filed with FDA a 510 (k) marketing application** ~~These future developments could include duration of the pandemic or other epidemic, new information concerning severity, efforts~~ for **Quell – CIPN** ~~widespread vaccination, treatment of those adversely affected, and other unanticipated developments~~. DPNCheck was launched in 2011 and is a nerve conduction test for peripheral neuropathies such as diabetic peripheral neuropathy. Our sales strategy for DPNCheck ~~targets~~ **has focused on** the U. S. ~~Medicare Advantage (~~MA ~~)~~ sector through our own commercial team **,** and physician offices and hospitals in Japan and China through distribution partners. The MA market ~~is currently experiencing~~ **experienced substantial** ~~uncertainty due to changes~~ **change during** ~~in several aspects of the program recently proposed by the CMS. On January 30,~~ 2023 ~~,~~ **when** CMS issued **new** ~~a final rule~~ **rules** ~~regarding~~ **on** the MA ~~Risk Adjustment Data Validation (~~RADV ~~)~~ program that is used to recover improper risk adjustment payments made to MA plans ~~.~~ **and** ~~Also~~ **also** ~~on February 1, 2023, CMS~~ issued its 2024 Medicare Advantage Advance Notice, which ~~proposed~~ **confirmed** substantial changes to the ~~Hierarchical Condition Categories (~~HCC ~~)~~ risk adjustment model ~~for calendar year 2024. The proposal includes changes that limit~~ **limiting** HCC codes for ~~some~~ **many** types of peripheral neuropathies. The ~~eventual~~ impact of these factors **on 2023 DPNCheck revenue was materially adverse. While we continue to support our customers** and **work to acquire new accounts** ~~related uncertainty is unclear; however~~, ~~there could be~~ **we do not expect** a ~~material effect on future~~ **near- term recovery from the decline in** DPNCheck ~~revenues~~ **revenue** ~~and margins. We have been advised that some of our customers may elect to pause or reduce, potentially substantially, the amount of DPNCheck tests they perform. We are unable at this time to predict with specificity the impact this may have on our revenues in future periods. Quell was launched in June 2015 and is a wearable neuromodulation device for the symptomatic relief and management of chronic pain indications. We are leveraging our core Quell technology into a portfolio of prescription wearable neurotherapeutics. Quell Fibromyalgia, the first product in this emerging portfolio, was launched in late 2022 as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity~~. Our future prospects are closely tied to our success with **Quell and** DPNCheck ~~and Quell~~, which, in turn, depend upon market acceptance and growth in future revenues and margins. We cannot assure you that our commercialization strategy will be successful. If our strategy is not successful, it could materially affect our revenues and results of operations. Our future success could be adversely affected by a number of factors, including: • inability to increase adoption of DPNCheck within the MA market and outside the United States; • regulatory inquiries or issues affecting our products; • unfavorable changes to current Medicare, Medicare Advantage and commercial payer payment policies; • changes to payor policies under the Patient Protection and Affordable Care Act; • inability to efficiently create market demand for prescription wearable neurotherapeutics based on Quell technology at profitable pricing and with efficient marketing; • manufacturing issues with Quell or our other products; • unfavorable experiences by patients and physicians using DPNCheck, Quell and our other products; and, • physicians' or patients' reluctance to alter their existing practices and adopt the use of our devices. If we are unable to expand exposure and market demand for DPNCheck and Quell, our ability to increase our revenues will be limited and our business prospects will be adversely affected. We will continue to incur operating losses until such time as sales of **Quell,** DPNCheck ~~, Quell~~ and other products or product candidates reach a mature level and we are able to generate sufficient revenue from their sale to meet our operating expenses. There can be no assurance that customers will adopt our technology and products, or that prospective customers will agree to pay for our products. In the event that we are not able to significantly increase the number of customers that purchase our products, or if we are unable to charge the necessary prices, our financial condition and results of operations will be materially and **adversely affected. If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third- party health care payers related to the use of our products other than Quell, their adoption and our future product sales will be materially** adversely affected. Widespread adoption of our diagnostic products by the medical community is unlikely to occur without a financial incentive from third- party payers for the use of these products. If health care providers are unable to obtain adequate reimbursement for procedures performed using these products, and if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly. Additionally, even if these products and procedures are adequately reimbursed by third- party payers today, adverse changes in payers future policies toward payment would harm our ability to market and sell our products. Third- party payers include governmental programs such as Medicare and Medicaid, private health insurers, workers' compensation programs and other organizations. Future regulatory action by CMS or other governmental agencies or negative clinical results may diminish reimbursement payments to physicians for performing procedures using our products. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not cover the procedures performed with our products or pay physicians an adequate amount for performing those procedures, if at all. Additionally, some private payers do not follow the Medicare guidelines and may reimburse for only a portion of these procedures or not at all. We are unable to predict what changes will be made in the reimbursement methods

used by private or governmental third- party payers. Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. The results of clinical studies of our products conducted to date and ongoing or future studies of our current, planned, or future products and product candidates may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Our interpretation of data and results from our clinical studies do not ensure that we will achieve similar results in future clinical studies. In addition, clinical data is often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in clinical studies have nonetheless failed to replicate results in later clinical studies. Products in later stages of clinical studies may fail to show the desired safety and efficacy despite having progressed through nonclinical studies. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical testing in addition to those we have planned. We rely on **third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates. We rely on** contract research organizations, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. Our clinical trials may be delayed, suspended, or terminated if: the quality or accuracy of the data obtained by the third parties on whom we rely is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or if for other reasons, these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines, or these third parties need to be replaced. If the third parties on whom we rely fail to perform, our development costs may increase, **and** our ability to obtain regulatory approval ~~,~~ and ~~consequently, to~~ commercialize our product candidates may be delayed or prevented altogether. We currently support medical institutions who are conducting clinical trials related to our products. While we believe that there are alternative approaches to ~~theses~~ **these** medical institutions, in the event that we seek such alternative sources we may not be able to enter into replacement arrangements without delays or incurring additional expenses. We rely on third- party manufacturers to manufacture components of our Quell, DPNCheck and ADVANCE systems. In the event that our manufacturers cease to manufacture sufficient quantities of our products or components in a timely manner and on terms acceptable to us, we would be forced to locate alternate manufacturers. Additionally, if our manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products, experience extraordinary price increases on parts essential to our products or otherwise fail to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or to locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products or components for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. While we have long- standing relationships with our primary suppliers for device components, electrodes and biosensors, these suppliers are, in turn, dependent on other manufacturers of electronic parts and components, and are therefore subject to supply ~~/~~ **and** demand risks of the electronic parts and components marketplace, and the potential for parts obsolescence. As a result, there is a risk that certain parts and components could be in short supply at a time when required by us or they could be discontinued and no longer available to us. ~~Supply of electronic parts and components is presently constrained on a worldwide basis. Situations of long lead times, stock- out, order repricing and cancellations are increasingly common.~~ We ~~are~~ **have** ~~experiencing~~ **experienced** ~~transient~~ **, from time to time,** inventory shortages on our products and essential parts. If any materially adverse changes in our relationships with manufacturers or parts suppliers occur, our ability to supply our customers will be severely limited until we are able to engage an alternate manufacturer or parts supplier or, if applicable, resolve any quality issues with our existing manufacturer. This situation could prevent us from delivering products to our customers in a timely manner, lead to decreased sales or increased costs, or harm our reputation with our customers. **If our manufacturers are unable to supply us with an adequate supply of product components, we could lose customers, our potential future growth could be limited and our business could be harmed.** In order for us to successfully expand our business, our contract manufacturers must be able to provide us with substantial quantities of components of our products in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our potential future growth ~~, coupled with the global supply chain constraints and disruptions caused by the COVID- 19 pandemic,~~ could strain the ability of our manufacturers to deliver products and obtain materials and components in sufficient quantities. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to obtain sufficient quantities of high **-** quality products to meet customer demand on a timely basis, we could lose customers, our growth may be limited and our business could be harmed. We commenced commercialization of Quell in June 2015 and we completed a DPNCheck product upgrade during 2022. We have additional product candidates and enhancements of our existing products in our R & D pipeline. We expect that advancing our pipeline products will require significant time and resources. We may not be successful in our commercialization efforts for any of the product candidates or product enhancements currently in our pipeline and we may not be successful in developing, acquiring, or in licensing additional product candidates, to the extent we decide to do so. If we are not successful in advancing new products through our development pipeline, the regulatory process and commercial launch, our business, financial condition, and results of operations will be adversely affected. A number of factors may adversely impact our gross margins on product sales and services, including: • shortages of ~~electric~~ **electronic** components resulting in higher prices or an inability to supply key parts; • low production volume which will result in high levels of overhead cost per unit of production; • increased material or labor costs; • increased service or warranty costs or the failure to reduce service or warranty costs; • increased price competition; • variation in the margins across products in a particular period; and • how well we execute on our strategic and operating plans. If we are unable to maintain or increase our gross margins on product sales, our results of operations could be adversely impacted, we may not achieve profitability and our stock price could decline. **If we lose any of our officers or key employees, our management and technical expertise could be weakened significantly.** Our success largely depends on the skills,

experience, and efforts of our executive officers, Shai N. Gozani, M. D., Ph. D., our founder, Chairman, President and Chief Executive Officer, and Thomas T. Higgins, our Senior Vice President and Chief Financial Officer. We do not maintain key person life insurance policies covering any of our employees. The loss of either of our executive officers could weaken our management and technical expertise significantly and harm our business. We are a small company with ~~27~~ **26** employees as of December 31, ~~2022~~ **2023** , and our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining our future performance. We may not be able to meet our future hiring needs or retain existing personnel, particularly given the challenges faced by our business. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel would materially harm our ability to compete effectively and grow our business. Our future business and financial success will depend, in part, on our ability to effectively market our products, including **Quell and** DPNCheck ~~and Quell~~ , and to enhance these products in response to customer demand **and feedback** . Developing new products and upgrades to existing and future products imposes burdens on our research and development department and our management. This process is costly, and we cannot assure you that we will be able to successfully develop new products or enhance our current products. We also may not be able to enter into relationships with other companies to sell additional products. In addition, as we develop the market for our products, future competitors may develop desirable product features earlier than we do which could make our competitors' products less expensive or more effective than our products and could render our products obsolete or unmarketable. If our product development efforts are unsuccessful, we will have incurred significant costs without recognizing the expected benefits and our business prospects may suffer. Our success depends on the successful development, regulatory clearance or approval (if required), introduction and commercialization of new generations of products, treatment systems, and enhancements to and / or simplification of existing products. **Quell and** DPNCheck ~~and Quell~~ must keep pace with, among other things, the products of our competitors. We are making significant investments in long-term growth initiatives. Such initiatives require significant capital commitments, involvement of senior management and other investments on our part, which we may be unable to recover. Our timeline for the development of new products or enhancements may not be achieved and price and profitability targets may not prove feasible. Commercialization of new products may prove challenging, and we may be required to invest more time and money than expected to successfully introduce them. Once introduced, new products may adversely impact orders and sales of our existing products, or make them less desirable or even obsolete. Compliance with regulations, competitive alternatives, and shifting market preferences may also impact the successful implementation of new products or enhancements. Our ability to successfully develop and introduce new products and product enhancements, and the revenues and costs associated with these efforts, may be affected by our ability to: • properly identify customer needs; • prove feasibility of new products in a timely manner; • educate physicians about the use of new products and procedures; • comply with internal quality assurance systems and processes timely and efficiently; • comply with regulatory requirements relating to our products, and limit the timing and cost of obtaining required regulatory approvals or clearances; • accurately predict and control costs associated with inventory overruns caused by phase- in of new products and phase- out of old products; • price new products competitively; • manufacture and deliver our products in sufficient volumes on time, and accurately predict and control costs associated with manufacture of the products; and • meet our product development plan and launch timelines. Even if customers accept new products or product enhancements, the revenues from these products may not be sufficient to offset the significant costs associated with making them available to customers. Failure to successfully develop, obtain regulatory approval or clearance for, manufacture or introduce new products or to complete these processes in a timely and efficient manner could result in delays that could affect our ability to attract and retain customers, or could cause customers to delay or cancel orders, causing our backlog, revenues and operating results to suffer. We currently do, and in the future may need to, compete directly and indirectly with a number of other companies that may have competitive advantages over us. Our diagnostic devices for nerve testing compete with companies that sell traditional nerve conduction study and electromyography equipment including Cadwell Laboratories, Inc. and Natus Medical Incorporated. These companies enjoy significant competitive advantages, including: • greater resources for product development, sales and marketing; • more established distribution networks; • greater name recognition; • more established relationships with health care professionals, customers and third- party payers; and • additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives. As we develop the market for wearable technology for chronic pain, we will be faced with competition from other companies that decide and are able to enter the market as well as competition from other forms of treatment for chronic pain. Some or all of our future competitors in the diagnostic nerve testing market and the chronic pain market may enjoy competitive advantages such as those described above. If we are unable to compete effectively against existing and future competitors, our sales will decline and our business will be harmed. **Cybersecurity incidents, security breaches and other disruptions could compromise our information, hinder our ability to perform essential activities, and expose us to financial claims and liabilities, which could cause our business and reputation to suffer.** In the ordinary course of our business, we collect and store sensitive data in our data centers, on our networks, including intellectual property, our proprietary business information, and that of our customers, suppliers and business partners, and personally identifiable information of our employees. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. **Similar risks exist with respect to our business partners and third- party providers, including suppliers, software and cloud- based service providers, that we rely upon for aspects of our information technology support services and certain administrative functions.** Any such **incident or** breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, disrupt our operations, damage our reputation, and cause a loss of confidence in our products and services, which could have a material adverse effect on our

business, financial condition, results of operations or cash flows. Future clinical studies or other articles regarding our existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor' s product is more accurate or effective than our products or that our products are not as accurate or effective as we claim or previous clinical studies have concluded. Additionally, physician associations or other organizations that may be viewed as authoritative or have an economic interest in nerve conduction studies and in related electrodiagnostic procedures or other procedures that may be performed using our products or in neurostimulation therapies using our devices could endorse products or methods that compete with our products or otherwise announce positions that are unfavorable to our products. Any of these events may negatively affect our sales efforts and result in decreased revenues. Foreign markets represented approximately **20 % and** 14 % of our revenues in **2023 and** 2022 ~~and 2021~~ **, respectively** . We are evaluating future expansion, particularly in Asia. Any such expansion will subject us to the possibility of new business risks, including: • failure to fulfill foreign regulatory requirements, if applicable, to market our products; • availability of, and changes in, reimbursement within prevailing foreign health care payment systems; • adapting to the differing business practices and laws in foreign countries; • difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign distributors or sales or marketing agents; • limited protection for intellectual property rights in some countries; • difficulty in collecting accounts receivable and longer collection periods; • costs of enforcing contractual obligations in foreign jurisdictions; • recessions in economies outside of the United States; • political instability and unexpected changes in diplomatic and trade relationships; • currency exchange rate fluctuations; and • potentially adverse tax consequences. If we are successful in introducing our products into foreign markets, we will be affected by these additional business risks, which may adversely impact our financial condition or results of operations. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments, and general managerial resources. Any efforts to introduce our products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Risks Related to Government Regulation and Other Legal Compliance Matters We sell medical devices that are subject to extensive regulation in the United States by the FDA with regard to manufacturing, labeling, sale, promotion, distribution, shipping and ongoing monitoring and follow- up. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first be cleared or approved by the FDA. Medical devices may be marketed only for the indications for which they are approved or cleared. The regulatory review process can be expensive and lengthy. The FDA' s process for granting 510 (k) clearance typically takes approximately three to six months, and for De Novo clearance approximately five months to one year. However, in both cases it can be significantly longer. The process for obtaining a ~~pre- market approval (~~ PMA ~~)~~ is much more costly and onerous. By law, the time period designated for the FDA' s review of a PMA is 180 days; however, this time is often extended and it is not uncommon for the PMA review process to take three years or longer from the time the application is filed with the FDA. The FDA may remove our devices from the market or enjoin them from commercial distribution if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510 (k) clearances, De Novo clearances or pre- market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. If any of these events occurs or if the FDA takes other enforcement actions, we may not be able to provide our customers with the products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs. We also are subject to numerous post- marketing regulatory requirements, including the FDA' s **(i)** quality system regulations, which relate to the design, manufacture, packaging, labeling, storage, installation and servicing of our products ~~,~~ **; (ii)** labeling regulations, medical device reporting regulations **;** and **(iii)** correction and removal reporting regulations. Third- party pharmacies, including online pharmacies, and other distributors of our products may also be subject to federal, state and local licensing, accreditation and other regulatory requirements. Our failure or the failure by any manufacturer, pharmacy or distributor of our products to comply with applicable regulatory requirements could result in enforcement action by the FDA or other regulators or it could result in delays in the distribution of our products. FDA enforcement actions relating to post- marketing regulatory requirements or other issues may include any of the following: • warning letters, untitled letters, fines, injunctions, product seizures, consent decrees and civil penalties; • requiring repair, replacement, refunds, customer notifications or recall of our products; • imposing operating restrictions, suspension or shutdown of production; • refusing our requests for 510 (k) clearance or PMA approval of new products, new intended uses, or modifications to existing products; • requesting voluntary rescission of 510 (k) clearances or withdrawing PMA approvals that have already been granted; and • criminal prosecution. If any of these events were to occur, they could harm our reputation, our ability to generate revenues and our profitability. Also, from time to time, legislation is introduced into Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of medical devices. FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. The FDA has publicly stated that it is reevaluating its longstanding 510 (k) review program. It is not clear when, or if, the program will be modified and what effect the modified review process will have on our ability to bring our product candidates to market. We and our contract manufacturers are required to comply with the FDA' s ~~quality system regulation, or~~ QSR ~~,~~ which is a complex regulation that governs the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR through periodic inspections. We cannot assure

you that our facilities or the facilities of the manufacturers of our products would pass any future inspection. If our facilities or any of the facilities of the manufacturers of our products fail an inspection, the manufacturing or distribution of our products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse inspection could result in a suspension or shutdown of our packaging and labeling operations and the operations of the manufacturers of our products or a recall of our products, or other administrative or judicial sanctions. If any of these events occurs, we may not be able to provide our customers with the quantity of products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs. Under the ~~Federal Trade Commission Act (~~ FTC Act ~~)~~, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, or injunctions affecting the manner in which we would be able to market Quell in the future. We are subject to the medical device reporting regulations, which require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or have malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to occur. We are also subject to the correction and removal reporting regulations, which require us to report to the FDA any field corrections and device recalls or removals that we undertake to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug and Cosmetic Act **(** ~~, or~~ FDCA ~~,~~ **)** caused by the device which may present a risk to health. In addition, the FDA and similar governmental agencies in other countries have the authority to require the recall of our products if there is a reasonable probability that the products would cause serious adverse health consequences or death. A government- mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers and could have a material adverse effect on our financial condition and results of operations. A federal law commonly known as the federal anti- kickback law, and several similar state laws, prohibit the payment of any remuneration that is intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. These laws constrain a medical device company' s sales, marketing and other promotional activities by limiting the kinds of business relationships and financial arrangements, including sales programs we may have with hospitals, pharmacies (including online pharmacies), physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other third- party payers that are false or fraudulent, or for items or services that were not provided as claimed. We rely on third **-** party health care organizations, pharmacies (including online pharmacies) and distributors to fulfill orders of our products. In addition, from time to time, we may provide coding and billing information as product support to purchasers of our products. Our relationships with health care organizations, pharmacies and other third parties could be scrutinized under federal and state health care laws such as the anti- kickback laws. Anti- kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be quite substantial including exclusion from participation in federal health care programs. A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care organizations. Some state statutes, such as the one in Massachusetts, impose an outright ban on gifts to physicians. These laws are often referred to as " gift ban " or " aggregate spend " laws and carry substantial fines if they are violated. Similar legislation, known as the Physician Payments Sunshine Act, was enacted by Congress ~~during~~ **in** 2014. In the event that we are found to have violated these laws or determine to settle a claim that we have done so, our business may be materially adversely affected as a result of any payments required to be made, restrictions on our future operations or actions required to be taken, damage to our business reputation or adverse publicity in connection with such a finding or settlement or other adverse effects relating thereto. Additionally, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations. There are a number of federal and state laws protecting the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U. S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996 ~~, or HIPAA~~. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Any failure or perceived failure by us or any third- party distributors, pharmacies, service providers, contractors or consultants to comply with privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, or transfer of sensitive information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including class action lawsuits, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of medical devices. The medical device industry historically has been litigious, and we face financial exposure to product liability claims if the use of our products were to cause or contribute to injury or death. Our products may be susceptible to claims of injury because their use involves the electric stimulation of a patient' s nerves. Although we maintain product liability insurance for our products and other commercial insurance, the coverage limits of these policies may not be adequate to cover future claims. We may be unable

to maintain sufficient product liability or other commercial insurance on acceptable terms or at reasonable costs, and this insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations. A product liability claim, regardless of its merit or eventual outcome, could result in substantial costs to us, a substantial diversion of management attention and adverse publicity. A product liability claim could also harm our reputation and result in a decline in revenues and an increase in expenses. We depend upon third parties for the manufacture of our products or components. Our products, particularly our electrodes, require a significant degree of technical expertise to produce. If these manufacturers fail to produce our products to specification, or if the manufacturers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised. If our products contain defects that cannot be repaired quickly, easily and inexpensively, we may experience: • loss of customer orders and delay in order fulfillment; • damage to our brand reputation; • increased cost of our warranty program due to product repair or replacement; • inability to attract new customers; • diversion of resources from our manufacturing and research and development departments into our service department; and • legal action. The occurrence of any one or more of the foregoing could harm our reputation and materially reduce our revenues and increase our costs and liabilities. Risks Related to Our Intellectual Property Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect these rights adequately. The risks and uncertainties that we face with respect to our patents and other related rights include the following: • the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents; • the claims of any patents that are issued may not provide meaningful protection; • we may not be able to develop additional proprietary technologies that are patentable; • other parties may challenge patents, patent claims or patent applications licensed or issued to us; and • other companies may design around technologies we have patented, licensed or developed. Our issued and filed patents for our wearable therapeutic products are recent. With regard to our legacy neurodiagnostic products, our issued design patents began to expire in 2015, and our issued utility patents began to expire in 2017. In particular, seven of our issued U. S. utility patents covering various aspects of the legacy neurodiagnostic business expired on the same day in 2017. Although the patent protection for material aspects of these products covered by the claims of the patents were lost at that time, we have additional patents and patent applications directed to other novel inventions that have patent terms extending **into 2024 and** beyond ~~2023~~. In addition, the laws of other countries may not protect our patent rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Many companies have encountered significant difficulties in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, including certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to medical devices, which could make it difficult for us to stop the infringement of our patent rights or the marketing of competing products in violation of our intellectual property and proprietary rights generally. For this or other reasons, we may not pursue or obtain patent protection in all major markets or may not obtain protection that enables us to prevent the entry of third parties onto the market. Additionally, proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, ~~could~~ put our patents at risk of being invalidated or interpreted narrowly, ~~could~~ put our patent applications at risk of not issuing and ~~could~~ provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, our patent rights underlying our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. If any of these events were to occur, our ability to compete in the market would be harmed. In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, confidentiality, nondisclosure and assignment of invention agreements and other contractual provisions and technical measures to protect our intellectual property rights. We rely on trade secrets to protect the technology and algorithms we use in our customer data processing and warehousing information system. While we currently require employees, consultants and other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements or a combination thereof where appropriate, any of the following could still occur: • the agreements may be breached or not enforced in a particular jurisdiction; • we may have inadequate remedies for any breach; • trade secrets and other proprietary information could be disclosed to our competitors; or • others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies. If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and our competitive position. We **may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market. We** rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in

which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to: • assert claims of infringement; • enforce our patents; • protect our trade secrets or know- how; or • determine the enforceability, scope and validity of the proprietary rights of others. Any lawsuits that we initiate could be expensive, take significant time and divert management' s attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events could harm our business, our ability to compete in the market or our reputation. Substantial litigation over intellectual property rights exists in the medical device industry. We expect that our products could be increasingly subject to third- party infringement claims as the number of competitors grows and the functionality of products and technology in different industry segments overlap. Third parties may currently have, or may eventually be issued, patents on which our products or technologies may infringe. Any of these third parties might make a claim of infringement against us. Any litigation regardless of its impact would likely result in the expenditure of significant financial resources and the diversion of management' s time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays or require us to develop non- infringing technology, make substantial payments to third parties, or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non- infringing technology or license the infringed or similar technology on a timely and cost- effective basis, our revenues may decrease substantially and we could be exposed to significant liability. Risks Related to Our Common Stock ~~In connection with our financial statement close process for the year ended December 31, 2022, we identified a material weakness in our internal control over financial reporting. A " material weakness " is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis. The material weakness identified during the audit of our financial statements for the year ended December 31, 2022 relates to inventory accounting. Specifically, we have concluded that our internal controls were not able to ensure the proper review and determination of inventory costing, and the valuation of our net realizable inventory. To address this material weakness, our management has taken, and continues to take, remedial actions. We have reviewed and are updating our internal control framework. We expanded our period- end closing process to require that the Corporate Controller perform and document a review of inventory costing and also prepare an analysis of inventory net realizable value, which analysis is required to be reviewed and approved by the Chief Financial Officer. Our remediation plan is underway; however, the elements of our remediation plan can only be fully accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects or that other material weaknesses and control deficiencies will not be discovered in the future. If our efforts are not successful or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis or help prevent fraud, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence or delisting and cause the market price of our shares to decline. We cannot assure you that the initiatives we have taken to date, or any initiatives we may take in the future, will be sufficient to avoid potential future material weaknesses.~~ Until such time as we are profitable, as to which we can make no assurance, we may need additional funds to develop our business and sustain our operations. We have sold shares of common stock, convertible preferred stock and warrants on several occasions in the past, and any additional sales of shares of our common stock or other securities exercisable into our common stock are likely to have a dilutive effect on some or all of our then existing stockholders. Resales of newly issued shares in the open market could also have the effect of lowering our stock price, thereby increasing the number of shares we may need to issue in the future to raise the same dollar amount and consequently further diluting our outstanding shares. The perceived risk associated with the possible sale of a large number of shares could cause some of our stockholders to sell their stock, thus causing the price of our stock to decline. In addition, actual or anticipated downward pressure on our stock price due to actual or anticipated issuances or sales of stock could cause some institutions or individuals to engage in short sales of our common stock, which may itself cause the price of our stock to decline. If our stock price declines, it may be difficult to raise additional capital and it could impair our ability to attract and retain qualified employees, reduce the liquidity of our common stock, and result in the delisting of our common stock from ~~The Nasdaq Stock Market LLC, or~~ Nasdaq. The trading price of our common stock has been highly volatile. For the two- year period ended December 31, ~~2022~~ **2023** , our stock price has fluctuated from a low of $ ~~1~~ **3** . ~~33~~ **05** to a high of $ ~~38~~ **59** . ~~75~~ **28** . The market price for our common stock will be affected by a number of factors, including: • the denial or delay of regulatory clearances or approvals for our products under development or receipt of regulatory approval of competing products; • our ability to accomplish clinical, regulatory and other product development and commercialization milestones and to do so in accordance with our timing estimates; • changes in policies affecting third- party coverage and reimbursement in the United States and other countries; • changes in government regulations and standards affecting the medical device industry and our products; • ability of our products to achieve market success; • the performance of third- party contract manufacturers and component suppliers; • actual or anticipated variations in our results of operations or those of our competitors; • announcements of new products, technological innovations or product advancements by us or our competitors; • developments with respect to patents and other intellectual property rights; • sales of common stock or other securities by us or our stockholders in the future; • additions or departures of key scientific or management personnel; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • trading volume of our common stock; • regulatory inquiries or developments affecting our products; • changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to

achieve analyst earnings estimates; • public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products; • decreases in market valuations of medical device companies; and • general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors. The stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Periods of volatility in the market price of a company' s securities can result in securities class action litigation against a company. If class action litigation is initiated against us, we may incur substantial costs and our management' s attention may be diverted from our operations, which could significantly harm our business. **We have, in the past, failed to satisfy certain continued listing requirements on Nasdaq and could fail to satisfy those requirements again in the future which could affect the market price of our common stock and liquidity and reduce our ability to raise capital. We have, in the past, failed to satisfy certain continued listing requirements on Nasdaq. For example, as previously disclosed, on August 8, 2023, we received a deficiency letter from the Nasdaq Listing Qualifications Department notifying us that because the closing bid price of our common stock had fallen below $ 1. 00 per share for 30 consecutive business days, we no longer met the bid price requirement. We were able to regain compliance with the minimum bid price requirement within the prescribed 180- day compliance period by effecting a reverse stock split, and** ~~Currently~~ **currently** , our common stock trades on ~~the~~ Nasdaq ~~Capital Market~~ . ~~If~~ **However, if** we fail to maintain compliance with any Nasdaq listing requirements **in the future** , including minimum bid price for our common stock, we could be delisted and our stock would be considered a penny stock under regulations of the ~~Securities and Exchange Commission, or~~ SEC ~~,~~ and would therefore be subject to rules that impose additional sales practice requirements on broker- dealers who sell our securities. The additional burdens imposed upon broker- dealers by these requirements could discourage broker- dealers from effecting transactions in our common stock, which could severely limit the market liquidity of our common stock and your ability to sell our securities in the secondary market. **The long- term effects of our recently completed reverse stock split on the market price of our common stock cannot be predicted with any certainty, and shares of our common stock have likely experienced decreased liquidity as a result of the reverse stock split. On November 21, 2023, we effected a reverse stock split of the Company' s common stock, at a ratio of 1- for- 8, to comply with Nasdaq' s minimum bid price requirement. The liquidity of our common stock has likely been adversely affected and may continue to be adversely affected by the reverse stock split given the reduced number of shares of our common stock that are now outstanding following the reverse stock split, particularly if the market price of our common stock does not increase from its recent decline after the reverse stock split. As a result of the lower number of shares outstanding following the reverse stock split, the market for our common stock may also become more volatile, which may lead to reduced trading and a smaller number of market makers for our common stock. The reverse stock split also increased the number of stockholders who own " odd lots " of less than 100 shares of common stock. A purchase or sale of less than 100 shares of common stock (an " odd lot " transaction) may result in incrementally higher trading costs through certain brokers, particularly " full service " brokers. Therefore, those stockholders who own fewer than 100 shares of common stock following the reverse stock split may be required to pay higher transaction costs if they sell their common stock. There can be no assurance that our share prices will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. The trading liquidity of our common stock may not improve. Anti- takeover provisions in our organizational documents and Delaware law, and the shareholder rights plan that we adopted in 2007 and updated in 2021, may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.** Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our Company or changes in our Board of Directors that our stockholders might consider favorable. Some of these provisions: • authorize the issuance of preferred stock which can be created and issued by the Board of Directors without prior stockholder approval, with rights senior to those of our common stock; • provide for a classified Board of Directors, with each director serving a staggered three- year term; • prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent; • provide for the removal of a director only with cause and by the affirmative vote of the holders of 75 % or more of the shares then entitled to vote at an election of our directors; and • require advance written notice of stockholder proposals and director nominations. We have also adopted a shareholder rights plan that could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, us or a large block of our common stock. A third party that acquires 15 % or more of our common stock could suffer substantial dilution of its ownership interest under the terms of the shareholder rights plan through the issuance of common stock to all stockholders other than the acquiring person. In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board of Directors or initiate actions that are opposed by our then- current Board of Directors, including a merger, tender offer, or proxy contest involving our Company. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline. We **do not intend to pay cash dividends. We** have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of potential gain for the foreseeable future.