Risk Factors Comparison 2025-03-11 to 2024-03-12 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

RISKS RELATED TO OUR BUSINESS AND THE INDUSTRY IN WHICH WE OPERATE Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including conditions that are outside of our control, such as the impact of health and safety concerns, including SARS- CoV- 2 (severe acute respiratory syndrome coronavirus 2) **pandemic** (~~"~~ **such as** COVID- 19 ~~"~~) ~~pandemic~~ and various variants, as well as military conflicts or wars (such as the ongoing conflicts between Russia and Ukraine and Israel and Palestine) that can cause exacerbated volatility and disruptions to various aspects of the global economy, and other disruptions to global supply chains. Each of these events has caused or may continue to result in extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, whether due to inflationary pressures or otherwise, could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third- party payers or our collaborators. Any of the foregoing could harm our business, and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business ~~. A pandemic, epidemic, or outbreak of an infectious disease, such as of COVID- 19 and subsequent variants, may materially and adversely affect our business and results of operations. Public health crises such as pandemics or similar outbreaks could adversely impact our business. In 2019, COVID- 19 surfaced in Wuhan, China and has since spread worldwide. The COVID- 19 pandemic is evolving and to date has led to the implementation of various responses including government- imposed quarantines, travel restrictions, and other public health safety measures. The effects of this outbreak on our business have included and could continue to include temporary closures of our providers and clinics and suspensions of elective surgical procedures. This has and could continue to impact our interactions and relationships with our customers. In addition to temporary closures of the providers and clinics that we serve, we could also experience temporary closures of the facilities of our suppliers, contract manufacturers, or other vendors in our supply chain, which could impact our business, interactions and relationships with our third- party suppliers and contractors, and results of operations. The extent to which COVID- 19 will impact our future business and the economy will also depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, adverse impacts of the Omicron COVID- 19 variant or other COVID- 19 variants, new information that will emerge concerning the severity of COVID- 19, and the actions to contain COVID- 19 or treat its impact, among others. Accordingly, we cannot predict the extent to which our financial condition, results of operations, and value of our common stock will be affected. The uncertainty surrounding the COVID- 19 outbreak has caused the Company to increase its inventory in anticipation of possible supply chain shortages related to the COVID- 19 virus. While we did not incur significant disruptions to our operations during 2023 and 2022, we are unable at this time to predict with confidence the impact that COVID- 19 will have on our business, financial position, and operating results in future periods due to numerous uncertainties~~ . Rapid technological change could cause our products to become obsolete and if we do not enhance our product offerings through our research and development efforts, we may be unable to effectively compete. The technologies underlying our products are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products, or processes with significant advantages over the products, services, and processes that we offer or are seeking to develop. Any such occurrence could have a material and adverse effect on our business, results of operations, and financial condition. We plan to enhance and broaden our product offerings in response to changing customer demands and competitive pressure and technologies, but we may not be successful. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to: ● properly identify and anticipate physician and patient needs; ● develop and introduce new products or product enhancements in a timely manner; ● adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; ● demonstrate the safety and efficacy of new products, including through the conduct of additional clinical trials; ● obtain the necessary regulatory clearances or approvals for new products or product enhancements; and ● achieve adequate coverage and reimbursement for our products. If we do not develop and, when necessary, obtain regulatory clearance or approval for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not be covered or reimbursed by government healthcare programs such as Medicare or private health plans, may not produce sales in excess of the costs of development, and / or may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features. ~~We~~ **11We** are dependent on reimbursement from third- party payers, most of whom are larger than we are and have substantially more employees and financial resources; changes in insurance reimbursement policies or application of them have resulted in decreased or delayed revenues. A large percentage of our revenues come from third- party payer reimbursement. Most of the third- party payers are large insurance companies with substantially more resources than we have. Upon delivery of our products to our patients, we directly bill the patients' private insurance companies or government payers for reimbursement. If the third-

party payers do not remit payment on a timely basis or if they change their policies to exclude or reduce coverage for our products, we would experience a decline in our revenue as well as cash flow. In addition, we may deliver products to patients and invoice based on past practices and billing experiences only to have third- party payers later deny coverage for such products. In some cases, our delivered product may not be covered pursuant to a policy statement of a third- party payer, despite a payment history with the third- party payer and benefits to the patients. A third- party payer may seek repayment of amounts previously paid for covered products. We maintain an allowance for provider discounts and amounts intended to cover legitimate requests for repayment. Failure to adequately identify and provide for amounts for resolution of repayment demands in our allowance for provider discounts could have a material adverse effect on our results of operations and cash flows. For government healthcare programs, if we identify a deficiency in prior claims or practices, we may be required to repay amounts previously reimbursed to us by government healthcare programs **, which could impact our reported revenues** . We frequently receive, and expect to continue to receive, refund requests from insurance providers relating to specific patients and dates of service. Billing and reimbursement disputes are very common in our industry. These requests are sometimes related to a few patients and other times include a significant number of refund claims in a single request which can accumulate to a significant amount. We review and evaluate these requests and determine if any refund is appropriate. During the adjudication process, we review claims where we are rebilling or pursuing additional reimbursement from that insurance provider. We frequently have significant offsets against such refund requests which may result in amounts that are due to us in excess of the amounts of refunds requested by the insurance providers. Therefore, at the time of receipt of such refund requests, we are generally unable to determine if a refund request is valid. Although we cannot predict whether or when a request for repayment or our subsequent request for reimbursement will be resolved, it is not unusual for such matters to be unresolved for an extended period of time. No assurances can be given with respect to our estimates for our allowance for provider discounts refund claim reimbursements and offsets or the ultimate outcome of the refund requests. We are dependent on our Medicare Supplier Number. We are required to have a Medicare Supplier Number in order to have the ability to bill Medicare for services provided to Medicare patients. Furthermore, all third- party and Medicaid contracts require us to have a Medicare Supplier Number. We are required to ~~12comply~~ -- **comply** with Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (" DMEPOS ") Supplier Standards in order to maintain such number. If we are unable to comply with the relevant standards, we could lose our Medicare Supplier Number. Without such number, we would be unable to continue our various third- party and Medicaid contracts. A significant portion of our revenues are dependent upon our Medicare Supplier Number, the loss of which would materially and adversely affect our business, financial condition, results of operations, and cash flows. The Center for Medicare and Medicaid Services (" CMS ") requires that all Durable Medical Equipment providers must be accredited by a CMS-approved accreditation organization. On February 1, 2013, we initially received accreditation from the Accreditation Commission for Health Care (" ACHC "), and we have remained accredited to date. If we lost our accredited status, our business, financial condition, revenues, and results of operations would be materially and adversely affected. ~~We~~ **12We** face periodic reviews and billing audits from governmental and private payers, and these audits could have adverse results that may negatively impact our business. As a result of our participation in the Medicaid program and our registration in the Medicare program, we are subject to various governmental reviews and audits to verify our compliance with these programs and applicable laws and regulations. We also are subject to audits under various government programs in which third- party firms engaged by CMS conduct extensive reviews of claims data and medical and other records to identify potential improper payments under the Medicare program. Private **payers** ~~pay sources~~ also reserve the right to conduct audits. If billing errors are identified in the sample of reviewed claims, the billing error can be extrapolated to all claims filed which could result in a larger overpayment than originally identified in the sample of reviewed claims. Our costs to respond to and defend reviews and audits may be significant and could have a material adverse effect on our business, financial condition, results of operations, and cash flows. Moreover, an adverse review or audit could result in: ● required refunding or retroactive adjustment of amounts we have been paid by governmental or private payers ; ● state or Federal agencies imposing fines, penalties, and other sanctions on us ; ● loss of our right to participate in the Medicare program, state programs, or one or more private payer networks ; or ● damage to our business and reputation in various markets. Any one of these results could have a material adverse effect on our business, financial condition, results of operations, and cash flows. Failure to secure and maintain adequate coverage and reimbursement from third- party payers could adversely affect acceptance of our products and reduce our revenues. The majority of our revenues come from third- party payers, primarily insurance companies. In the U. S., private payers cover the largest segment of the population, with the remainder either uninsured or covered by governmental payers. The majority of the third- party payers outside the U. S. are government agencies, government sponsored entities, or other payers operating under significant regulatory requirements from national or regional governments. Third- party payers may decline to cover and reimburse certain procedures, supplies, or services. Additionally, some third- party payers may decline to cover and reimburse our products for a particular patient even if the payer has a favorable coverage policy addressing our products or previously approved reimbursement for our products. Furthermore, private and government payers may consider the cost of a treatment in approving coverage or in setting reimbursement for the treatment. Private and government payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of governments. Adoption of additional price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our revenues and operating results. If third- party payers do not consider our products or the combination of our products with additional ~~13treatments~~ -- **treatments** to be cost- justified under a required cost- testing model, they may not cover our products for their populations or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Reimbursement for the treatment of patients with medical devices is governed by complex mechanisms. These mechanisms vary widely among countries, can be informal, somewhat unpredictable, and evolve constantly, reflecting the efforts of these countries to reduce public spending on healthcare. As a result, obtaining and

maintaining reimbursement for the treatment of patients with medical devices has become more challenging. We cannot guarantee that the use of our products will receive reimbursement approvals and cannot guarantee that our existing reimbursement approvals will be maintained in any country. Our failure to secure or maintain adequate coverage or reimbursement for our products by third- party payers in the U. S. or in the other jurisdictions in which we market our products could have a material adverse effect on our business, revenues, and results of operations and cause our stock price to decline. ~~We~~ **13We** may not be successful in maintaining the reimbursement codes necessary to facilitate accurate and timely billing for our products or physician services attendant to our products. Third- party payers, healthcare systems, government agencies, or other groups often issue reimbursement codes to facilitate billing for products and physician services used in the delivery of healthcare. If we are unable to maintain the Healthcare Common Procedure Coding System codes (" HCPCS codes ") for physician services related to our products, our revenues and results may be affected by the absence of such HCPCS codes, as physicians may be less likely to prescribe the therapy when there is no certainty that adequate reimbursement will be available for the time, effort, skill, practice expense, and malpractice costs required to provide the therapy to patients. Outside the United States, we have not secured codes to describe our products or to document physician services related to the delivery of therapy using our products. The failure to obtain and maintain these codes could affect the growth of our business. ~~We at times have concentrations of credit risk with third- party payers; failure to collect these and other billed receivables could adversely affect our cash flows and results of operations. At December 31, 2023 the Company did not have gross receivables from any third- party payer which made up over 10 % of the accounts receivable balance. The Company had gross receivables from one third- party payer at December 31, 2022, which made up approximately 14 % of the accounts receivable balance.~~ Future changes in coverage and reimbursement policies for our products or reductions in reimbursement rates for our products by third party payers could adversely affect our business and results of operations. In the United States, our products are prescribed by physicians for their patients. Based on the prescription, which we consider an order, we submit a claim for payment directly to third- party payers such as private commercial insurance carriers, government payers, and others as appropriate, and the third- party payer reimburses us directly. **Practices and policies around payment of the claims we submit can vary over time, which could impact our results of operations from quarter to quarter.** Federal and state statutes, rules, or other regulatory measures that restrict coverage of our products or reimbursement rates could have an adverse effect on our ability to sell or rent our products or cause physical therapists and physicians to dispense and prescribe alternative, lower- cost products **, which could negatively affect our revenues** . There are significant estimating risks associated with the amount of revenue, related refund liabilities, accounts receivable, and provider discounts that we recognize, and if we are unable to accurately estimate these amounts, it could impact the timing of our revenue recognition and cash collections, which have a significant impact on our operating results, or lead to a restatement of our financial results. There are significant risks associated with the estimation of the amount of revenues, related refund liabilities, accounts receivable, and provider discounts that we recognize in a reporting period. The billing and collection process is complex due to ongoing insurance coverage changes, geographic coverage differences, differing interpretations of coverage, differing provider discount rates, and other third- party payer issues. Determining applicable primary and secondary coverage for our customers at any point in time, together with the changes in patient coverage that occur each month, require complex, resource- intensive processes. Errors in determining the correct coordination of benefits may result in refunds to payers. Revenues associated with government programs are also subject to estimating risk related to the amounts not paid by the primary government payer that will ultimately be collectable from other ~~14government~~ -- **government** programs paying secondary coverage, the patient' s commercial health plan secondary coverage or the patient. Collections, refunds, and pay or retractions typically continue to occur for up to three years and longer after our products are provided. While we typically look to our past experience in collections with a payer in estimating amounts expected to be collected on current billings, recent trends and current changes in reimbursement practice, the overall healthcare environment, and other factors nonetheless could ultimately impact the amount of revenues recorded and the receivables collected. If our estimates of revenues, related refund liabilities, accounts receivable, or provider discounts are materially inaccurate, it could impact the timing of our revenue recognition and have a significant impact on our operating results. It could also lead to a restatement of our financial results. ~~Tax~~ **14Tax** laws and regulations require compliance efforts that can increase our cost of doing business. Changes to these laws and regulations could impact financial results. We are subject to a variety of tax laws and regulations in the jurisdictions in which we do business. Maintaining compliance with these laws can increase our cost of doing business **,** and failure to comply could result in audits or the imposition of fines or penalties. Further, our future effective tax rates in any of these jurisdictions could be affected, positively or negatively, by changing tax priorities, changes in statutory rates, or changes in tax laws or the interpretation thereof. The most significant recent example of this is the impact of the U. S Tax Cuts and Jobs Act of 2017 (the " Tax Act ") which was enacted on December 22, 2017. These changes significantly revised the ongoing U. S. corporate income tax law by lowering the U. S. federal corporate income tax rate from 35 % to 21 %, implementing a territorial tax system, imposing a one- time tax on foreign unremitted earnings, and setting limitations on deductibility of certain costs, among other things. The Company has implemented the Tax Act and does not expect any significant changes related to the Tax Act at this time. The impact of healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown but may harm our business. Our revenue is dependent on the healthcare industry and could be affected by changes in healthcare spending and policy. The healthcare industry is subject to changing political, regulatory, and other influences. The Patient Protection and Affordable Care Act (" PPACA ") made major changes in how healthcare is both delivered and reimbursed, and increased access to health insurance benefits to the uninsured and underinsured population of the United States. The PPACA, among other things, increased the number of individuals with Medicaid and private insurance coverage, implemented reimbursement policies that tie payment to quality, facilitated the creation of accountable care organizations that may use capitation and other alternative payment methodologies, strengthened enforcement of fraud and abuse laws, and encouraged the use of information technology. Such

changes in the regulatory environment may also result in changes to our payer mix that may affect our operations and net revenue. Certain provisions of the PPACA authorize voluntary demonstration projects, which include the development of bundling payments for acute, inpatient hospital services, physician services, and post- acute services for episodes of hospital care. Further, the PPACA may negatively impact payers by increasing medical costs generally, which could have an effect on the industry and potentially impact our business and revenue as payers seek to offset these increases by reducing costs in other areas. The full impact of these changes on us cannot be determined at this time. We are also impacted by the Medicare Access and CHIP Reauthorization Act, under which physicians must choose to participate in one of two payment formulas, Merit-Based Incentive Payment System (“ MIPS ”) or Alternative Payment Models (“ APMs ”). Beginning in 2019, MIPS allows eligible physicians to receive upward or downward adjustments to their Medicare Part B payments based on certain quality and cost metrics, among other measures. As an alternative, physicians can choose to participate in an Advanced APM. Advanced APMs are exempt from the MIPS requirements, and physicians who are meaningful participants in APMs will receive bonus payments from Medicare pursuant to the law. In addition, current and prior healthcare reform proposals have included the concept of creating a single payer or public option for health insurance. If enacted, these proposals could have an extensive impact on the healthcare industry, including us. We are unable predict whether such reforms may be enacted or their impact on our operations. ~~15We~~ **We** expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments and other third- party payers will pay for healthcare services, which could harm our business, financial condition, and results of operations. ~~The~~ **15The** Patient Protection and Affordable Care Act of 2010 has had an impact on our business **,** which may be in part beneficial and in part detrimental. In March 2010, broad federal healthcare reform legislation was enacted in the United States. This legislation did not become effective immediately in total and may be modified prior to the effective date of some provisions. This legislation has had an impact on our business in a variety of ways including increased number of Medicaid recipients, increased number of individuals with commercial insurance, additional audits conducted by public health insurance plans such as Medicaid and Medicare, changes to the rules that govern employer group health insurance, and other factors that influence the acquisition and use of health insurance from private and public payers. This legislation has resulted in a change in reimbursement for certain durable medical equipment. We believe the new healthcare legislation and these changes to reimbursement have caused uncertainty with prescribers, which we believe contributed to our drop in orders and revenue during 2013 and 2014 and the lack of any significant increase in 2015. Orders and revenue increased in 2016 through ~~2023~~ **2024** ; however, we are currently unable to determine whether such trend will continue in future periods or whether the healthcare reform legislation will have other adverse consequences to our business and results of operations. To the extent prescribers write fewer prescriptions for our products or there is an adverse change to insurance reimbursement for our products, due to the new law or otherwise, our revenue and profitability will be materially adversely affected. The uncertainty of continuing healthcare changes and regulations may negatively affect our business. There is some doubt on the continuation of the Affordable Care Act and the legislation that the current Congress will enact to replace it, if any. Because we cannot be certain about the continuation of the Affordable Care Act or any changes or replacements thereto, even if the Affordable Care Act remains the law of the land, there is also some doubt whether the President will support it or take regulatory action to negatively impact its benefits. The amount of uncertainty creates concern on our customers’ willingness to buy products which may or may not be covered by future healthcare benefits even if they are covered currently. 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 subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti- Kickback Statute, the federal Stark Law, and the federal False Claims Act. 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. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. 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. 16The federal Ethics in Patient Referrals Act of 1989, commonly known as the “ Stark Law ”, prohibits, subject to certain exceptions, physician referrals of Medicare and, as applicable under state law, Medicaid patients to an entity providing certain “ designated health services ” if the physician or an immediate family member has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing any good or service furnished pursuant to an unlawful referral. Various states have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state. The federal False Claims Act 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. The False Claims Act defines “ knowingly ” to include actual knowledge, acting in deliberate ignorance of the truth or falsity of information, or acting in deliberate disregard of the truth or falsity of information. False Claims Act liability includes liability for reverse false claims for avoiding or decreasing an

obligation to pay or transmit money to the government. This includes False Claims Act liability for failing to report and return overpayments within 60 days of the date on which the overpayment is " identified ". Penalties under the False Claims Act can include exclusion from the Medicare program. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Suits filed under the False Claims Act, 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 False Claims Act action. When an entity is determined to have violated the federal False Claims Act, 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 False Claims Act. HIPAA, and its implementing regulations, also created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. From time to time, the Company has been and is involved in various governmental audits, investigations, and reviews related to its operations. Reviews and investigations can lead to government actions, resulting in the assessment of damages, civil or criminal fines or penalties, or other sanctions, including restrictions or changes in the way we conduct business, loss of licensure, or exclusion from participation in Medicare, Medicaid, or other government programs. Additionally, as a result of these investigations, healthcare providers and entities may face litigation or have to agree to settlements that can include monetary penalties and onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement, or Corporate Integrity Agreement (" CIA "). If we fail to comply with applicable laws, regulations, and rules, the Company' s financial condition and results of operations could be adversely affected. Furthermore, becoming subject to these governmental investigations, audits, and reviews may result in substantial costs and divert management' s attention from the business as we cooperate with the government authorities, regardless of whether the particular investigation, audit, or review leads to the identification of underlying issues. 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 Medicare, Medicaid, and other government healthcare reimbursement programs, and the curtailment or restructuring of operations **. Healthcare Fraud and AbuseOur operations may be subject to federal and state healthcare laws and regulations including fraud and abuse laws, such as anti- kickback and false claims laws, data privacy and security laws and transparency laws related to payments and / or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. The federal Anti- Kickback Law prohibits unlawful inducements for the referral of business reimbursable under federally- funded healthcare programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The federal Anti- Kickback Law is subject to evolving interpretations. For example, the 17government has enforced the federal Anti- Kickback Law to reach large settlements with healthcare companies based on, among other things, inappropriate consultant arrangements with physicians or questionable joint venture arrangements. The majority of states also have anti- kickback laws, which establish similar prohibitions that may apply to items or services reimbursed by any third- party payer, including commercial insurers. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Health Care Reform Law, among other things, amended the intent requirement of the federal Anti- Kickback Law and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Health Care Reform Law provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Law constitutes a false or fraudulent claim for purposes of the civil False Claims Act and certain criminal healthcare fraud statutes. Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U. S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government is using the civil False Claims Act, and the accompanying threat of significant liability, in its investigations of healthcare providers and suppliers throughout the country for a wide variety of Medicare billing practices and has obtained multi- million and multi- billion dollar settlements in addition to individual criminal convictions. In addition, off- label promotion has been pursued as a violation of the federal False Claims Act. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their independent medical judgment, we are prohibited from promoting products for such off- label uses. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and suppliers' compliance with the healthcare reimbursement rules and fraud and abuse laws. Additionally, the majority of states in which we market our products have similar fraud and abuse laws, such as anti- kickback, false claims, anti- fee splitting and self- referral laws, which may apply to items or services reimbursed by any third- party payer, including commercial insurers, and violations may result in substantial civil, criminal and**

administrative penalties. The Health Care Reform Law also included the federal Physician Payments Sunshine Act, which requires device manufacturers for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program to disclose annually to CMS any " transfer of value " made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other licensed health care practitioners, and teaching hospitals. Such information is now made publicly available in a searchable format, and device manufacturers are now required to report and disclose any investment interests held by physicians and their family members during the preceding calendar year. Failure to submit required information may result in significant civil monetary penalties for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Additionally, the commercial compliance environment is continually evolving in the healthcare industry, and some states, including California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare providers. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Our business operations may also be subject to certain federal and state laws regarding the use and disclosure of individually identifiable health information, such as the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, which impose obligations on certain entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information. To enforce compliance with the federal laws, the U. S. Department of Justice, or DOJ, has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to an unprecedented level of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource- consuming. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, the company may be required to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. The U. S. and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased U. S. government oversight and enforcement of the Foreign Corrupt Practices Act. Whenever a governmental authority concludes that we are not in compliance with applicable laws or regulations, that authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose 18operating restrictions, inform other agencies of ongoing or findings of investigations, enjoin future violations and assess civil penalties against us or our officers or employees and can recommend criminal prosecution. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of devices we distribute. If a governmental authority were to conclude that we are not in compliance with applicable fraud and abuse laws and regulations, we and our officers and employees could be subject to severe penalties including, for example, civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and the results of our operations. It is uncertain whether and how future legislation could affect prospects for our products or what actions federal, state or private payers for health care treatment and services may take in response to any such health care reform proposals or legislation. Claims made against us from time to time can result in litigation that could distract management from our business activities and result in significant liability or damage to our brand. As a company with expanding operations, we increasingly face the risk of litigation and other claims against us. We have no such claims at present. Litigation and other claims may arise in the ordinary course of our business and include employee claims, commercial disputes, landlord- tenant disputes, intellectual property issues, product- oriented allegations and slip and fall claims. These claims can raise complex factual and legal issues that are subject to risks and uncertainties and could require significant management time. Litigation and other claims against us could result in unexpected expenses and liabilities, which could materially affect our operations and our reputation. In addition, the medical device industry is characterized by extensive litigation and, from time to time, we are the subject of various claims. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims against us could result in payment of significant monetary damages and / or injunctive relief. Litigation with customers, payers, employees and others could harm our reputation and impact operating results. In the ordinary course of business, we may be involved in lawsuits and regulatory actions with customers, payers, employees and others. These actions may involve claims for, among other things, compensation for alleged personal injury and product liability claims. Additionally, we may be subject to employment- related claims alleging discrimination, harassment, wrongful termination and wage issues, including those relating to overtime compensation. We are susceptible to claims filed by customers alleging responsibility for breaches of contract or from product defects, and we are also subject to lawsuits filed by patent holders alleging patent infringement. These types of claims, as well as other types of lawsuits to which we are subject from time to time, can distract management' s attention from core business operations and impact operating results, particularly if a lawsuit results in an unfavorable outcome, or could harm the Company' s reputation with customers, employees, investors and others . Hospitals and clinicians may not buy, prescribe, or use our products in sufficient numbers, which could result in decreased revenues and profits. Hospitals and clinicians may not accept any of our products as effective, reliable, or cost- effective. Factors that could prevent such institutional patient acceptance include: ● if patients

conclude that the costs of these products exceed the cost savings associated with the use of these products; ● if patients are financially unable to purchase these products; ~~17~~ ● if adverse patient events occur with the use of these products, generating adverse publicity; ● if we lack adequate resources to provide sufficient education and training to our patients; **19** ● if frequent product malfunctions occur, leading clinicians to believe that the products are unreliable; ● uncertainty regarding or change in government or third- party payer reimbursement policies for our products; and ● if physicians or other health care providers believe that our products will not be reimbursed by insurers or decide to prescribe competing products. Because our sales are dependent on prescriptions from physicians, if any of these or other factors result in fewer prescriptions for our products being written, we will have reduced revenues and may not be able to fully fund our operations. Although we experienced an increase in orders for our ZMI products during **2024 and** 2023 ~~and 2022~~ compared to prior years, we can make no assurances that demand for our products will not decline in future periods. Any new competitor could be larger than us and have greater financial and other resources than we do, and those advantages could make it difficult for us to compete with them. Many competitors to our products may have substantially greater financial, technical, marketing, and other resources. Competition could result in fewer orders, reduced gross margins, and loss of market share. Our products are regulated by the FDA in the United States. Competitors may develop products that are substantially equivalent to our FDA- cleared products, thereby using our products as predicate devices to more quickly obtain FDA approval for their own products. If overall demand for our products should decrease, it could have a material adverse effect on our operating results. Substantial competition is expected in the future in the area of stroke rehabilitation that may directly compete with our NeuroMove product. These competitors may use standard or novel signal processing techniques to detect muscular movement and generate stimulation to such muscles. Other companies may develop rehabilitation products that perform better and / or are less expensive than our products, which could have a material adverse effect on our operating results. Failure to keep pace with the latest technological changes could result in decreased revenues. The market for some of our products is characterized by rapid change and technological improvements. Failure to respond in a timely and cost- effective way to these technological developments could result in serious harm to our business and operating results. We have derived, and we expect to continue to derive, a substantial portion of our revenues from the development and sale of products in the medical device industry. As a result, our success will depend, in part, on our ability to develop and market product offerings that respond in a timely manner to the technological advances of our competitors, evolving industry standards, and changing patient preferences. There is no assurance that we will keep up with technological improvements. Our business could be adversely affected by reliance on sole suppliers. Notwithstanding our current multiple supplier approach, certain essential product components may be supplied in the future by sole, or a limited group of, suppliers. Most of our products and components are purchased through purchase orders rather than through long- term supply agreements, and large volumes of inventory may not be maintained. There may be shortages and delays in obtaining certain product components. Disruption of the supply or inventory of components could result in a significant increase in the costs of these components or could result in an inability to meet the demand for our products. In addition, if a change in the manufacturer of a key component is required, qualification of a new supplier may result in delays and additional expenses in meeting customer demand for products. These factors could adversely affect our revenues and ability to retain our experienced sales force. ~~18A~~ **20A** third- party manufacturer' s inability to produce our products' components on time and to our specifications could result in lost revenue. Third- party manufacturers assemble and manufacture components of the NexWave and NeuroMove and some of our other products to our specifications. The inability of a manufacturer to ship orders of our products in a timely manner or to meet our quality standards could cause us to miss the delivery date requirements of our patients for those items, which could result in cancellation of orders, refusal to accept deliveries, or a reduction in purchase prices, any of which could have a material adverse effect on our revenues. Because of the timing and seriousness of our business, and the medical device industry in particular, the dates on which patients need and require shipments of products from us are critical. Further, because quality is a leading factor when patients, doctors, health insurance providers, and distributors accept or reject goods, any decline in quality by our third- party manufacturers could be detrimental not only to a particular order, but also to our future relationship with that particular patient. We could experience cost increases or disruptions in supply of raw materials or other components used in our products. Our third- party manufacturers that assemble and manufacture components for our products expect to incur significant costs related to procuring raw materials required to manufacture and assemble our product. The prices for these raw materials fluctuate depending on factors beyond our control, including market conditions and global demand for these materials and could adversely affect our business, prospects, financial condition, results of operations, and cash flows. Further, any delays or disruptions in our supply chain could harm our business. For example, COVID- 19, including associated variants, could cause disruptions to and delays in our operations, including shortages and delays in the supply of certain parts, including semiconductors, materials and equipment necessary for the production of our products, and the internal designs and processes we or third- parties may adopt in an effort to remedy or mitigate impacts of such disruptions and delays could result in higher costs. In addition, our business also depends on the continued supply of battery cells for our products. We are exposed to multiple risks relating to availability and pricing of quality battery cells. These risks include: ● the inability or unwillingness of battery cell manufacturers to build or operate battery cell manufacturing plants to supply the numbers of battery cells (including the applicable chemistries) required to support the growth of the electric or plug- in hybrid vehicle industry as demand for such cells increases; ● disruption in the supply of battery cells due to quality issues or recalls by the battery cell manufacturers; and ● an increase in the cost or decrease in the available supply of raw materials used in battery cells, such as lithium, nickel, and cobalt. Furthermore, currency fluctuations, tariffs, or shortages in petroleum and other economic or political conditions may result in significant increases in freight charges and raw material costs. Substantial increases in the prices for raw materials or components would increase our operating costs and could reduce our margins. We depend upon third parties to manufacture and to supply key semiconductor chip components necessary for our products. We do not have long- term agreements with our semiconductor chip manufacturers and suppliers, and if these

manufacturers or suppliers become unwilling or unable to provide an adequate supply of semiconductor chips, with respect to which there is a global shortage, we would not be able to find alternative sources in a timely manner and our business would be adversely impacted. Semiconductor chips are a vital input component to the electrical architecture of our products, controlling wide aspects of the products' operations. Many of the key semiconductor chips we use in our products come from limited or single sources of supply, and therefore a disruption with any one manufacturer or supplier in our supply chain would have an adverse effect on our ability to effectively manufacture and timely deliver our products. We do not have any long- term supply contracts with any suppliers and purchase chips on a purchase order basis. Due to our reliance on these semiconductor chips, we are subject to the risk of shortages and long lead times in their supply. We are in the process of identifying alternative manufacturers for semiconductor chips. We have in the past experienced, and may in the future experience, semiconductor chip shortages, and the availability and cost of these components would be difficult to predict. For example, our manufacturers may experience temporary or permanent disruptions in their manufacturing operations due to equipment breakdowns, labor strikes or shortages, natural disasters, component or material shortages, cost increases, acquisitions, insolvency, changes in legal or regulatory requirements, or other similar problems. ~~19In~~ **21In** particular, increased demand for semiconductor chips in 2020, due in part to the COVID- 19 pandemic and increased demand for consumer electronics that use these chips, resulted in a severe global shortage of chips in 2021 and 2022. As a result, our ability to source semiconductor chips to be used in our products has been adversely affected. This shortage may result in increased chip delivery lead times, delays in the production of our products, and increased costs to source available semiconductor chips. To the extent this semiconductor chip shortage continues, and we are unable to mitigate the effects of this shortage, our ability to deliver sufficient quantities of our products to fulfill our preorders and to support our growth through sales to new customers would be adversely affected. In addition, we may be required to incur additional costs and expenses in managing ongoing chip shortages, including additional research and development expenses, engineering design, and development costs in the event that new suppliers must be onboarded on an expedited basis. Further, ongoing delays in production and shipment of products due to a continuing shortage of semiconductor chips may harm our reputation and discourage additional preorders and sales, and otherwise materially and adversely affect our business and operations. If we need to replace manufacturers, our expenses and cost of goods could increase, resulting in ~~low~~ **lower** profit margins. We compete with other companies for the production capacity of our manufacturers and import quota capacity. Some of these competitors have greater financial and other resources than we have and thus have an advantage in the competition for production and import quota capacity. If we experience a significant increase in demand, or if we need to replace an existing manufacturer, we may have to expand our third- party manufacturing capacity. We cannot assure that this additional capacity will be available when required on terms that are acceptable to us or similar to existing terms, which we have with our manufacturers, either from a production standpoint or a financial standpoint. We enter into a number of purchase order commitments specifying a time for delivery, method of payment, design and quality specifications, and other standard industry provisions, but we do not have long- term contracts with any manufacturer. None of the manufacturers we use produce our products exclusively. Should we be forced to replace one or more of our manufacturers, we may experience increased costs or an adverse operational impact due to delays in distribution and delivery of our products to our patients, which could cause us to lose patients or lose revenue because of late shipments. We are a relatively small company with a limited number of products and staff. Sales fluctuations and employee turnover may adversely affect our business. We are a relatively small company. Consequently, compared to larger companies, sales fluctuations could have a greater impact on our revenue and profitability on a quarter- to- quarter and year- to- year basis, and delays in patient orders could cause our operating results to vary significantly from quarter- to- quarter and year- to- year. In addition, as a small company we have limited staff and are heavily reliant on certain key personnel to operate our business. If a key employee were to leave the company, it could have a material impact on our business and **our** results of operations, as we might not have sufficient depth in our staffing to fill the role that was previously being performed. A delay in filling the vacated position could put a strain on existing personnel, result in a failure to satisfy our contractual obligations, or to effectively implement our internal controls, which could materially harm our business. If we are unable to retain the services of Mr. Sandgaard or if we are unable to successfully recruit qualified managerial and sales personnel, we may not be able to continue our operations. Our success depends to a significant extent upon the continued service of Mr. Thomas Sandgaard, our Chief Executive Officer, Founder, and beneficial owner of approximately 50 % of our outstanding stock as of February 28, ~~2024~~ **2025** . Loss of the services of Mr. Sandgaard could have a material adverse effect on our growth, revenues, and prospective business. There is currently no employment agreement with Mr. Sandgaard. We do not maintain key- man insurance on the life of Mr. Sandgaard. In addition, to successfully implement and manage our business plan, we will be dependent upon, among other things, successfully retaining and recruiting qualified managerial and sales personnel. Competition for qualified individuals is intense. Various factors, such as marketability of our products, our reputation, our liquidity, and sales commission structure can affect our ability to find, attract, or retain sales personnel. There can be no assurance that we will be able to find and attract qualified new employees and sales representatives and retain existing employees and sales representatives. ~~20We~~ **22We** need to maintain insurance coverage, which could become very expensive or have limited availability. Our marketing and sales of medical device products create an inherent risk of claims for product liability. As a result, we carry product liability insurance and will continue to maintain insurance in amounts we consider adequate to protect us from claims. We cannot, however, be assured that we have resources sufficient to satisfy liability claims in excess of policy limits if required to do so. Also, if we are subject to such liability claims, there is no assurance that our insurance provider will continue to insure us at current levels or that our insurance rates will not substantially rise in the future, resulting in increased costs to us or forcing us to either pay higher premiums or reduce our coverage amounts, which would result in increased liability to claims. Although we do not manufacture the products we distribute, if one of the products distributed by us proves to be defective or is misused by a health care practitioner or patient, we may be subject to liability that could adversely affect our financial condition and results of operations. Although we do not manufacture the products that we

distribute, a defect in the design or manufacture of a product distributed or serviced by us, or a failure of a product distributed by us to perform for the use specified, could have a material and adverse effect on our reputation in the industry and subject us to claims of liability for injuries and otherwise. Misuse of the product distributed by us by a practitioner or patient that results in injury could similarly subject us to liability. Any substantial underinsured loss could have a material and adverse effect on our business, financial condition, results of operations, and cash flows. Furthermore, any impairment of our reputation could have a material and adverse effect on our revenues and prospects for future business. We depend upon obtaining regulatory clearance of new products and / or manufacturing operations we develop and maintain clearances of current products; failure to obtain or maintain such regulatory clearances could result in increased costs, lost revenue, penalties, and fines. Before marketing certain new products, we will need to complete one or more clinical investigations of each product. There can be no assurance that the results of such clinical investigations will be favorable to us. We may not know the results of any study, favorable or unfavorable to us, until after the study has been completed. Such data must be submitted to the FDA as part of any regulatory filing seeking clearance to market the product. Even if the results are favorable, the FDA may dispute the claims of safety, efficacy, or clinical utility and not allow the product to be marketed. The sales price of the product may not be enough to recoup the amount of our investment in conducting the investigative studies, and we may expend significant funds on research and development on products that are rejected by the FDA. Some of our products are marketed based upon our interpretation of FDA regulation allowing for changes to an existing device. If our interpretations are incorrect, we could suffer consequences that could have a material adverse effect on our results of operations and cash flows and could result in fines and penalties. There can be no assurance that we will have the financial resources to complete development of any new products, complete the regulatory clearance process, or maintain regulatory compliance of existing products. We may not be able to obtain clearance of a 510 (k) pre- market notification or grant of a de novo classification request or approval of a pre- market approval application with respect to any products on a timely basis, if at all. If timely FDA clearance or approval of new products is not obtained, our business could be materially adversely affected. Clearance of a 510 (k) pre- market notification or de novo application may also be required before marketing certain previously marketed products, which have been modified after they have been cleared. Should the FDA so require, the filing of a new 510 (k) pre- market notification for the modification of the product may be required prior to marketing any modified device. To determine whether adequate compliance has been achieved, the FDA may inspect our facilities at any time. Such compliance can be difficult and costly to achieve and maintain. Our compliance status may change due to future changes in, or interpretations of, FDA regulations or other regulatory agencies. Such changes may result in the FDA withdrawing marketing clearance or requiring or requesting product recall. In addition, any changes or modifications to a device or its intended use may require us to reassess compliance with good manufacturing practices guidelines, potentially interrupting the marketing and sale of products. We may also fail to comply with complex FDA regulations due to their complexity or otherwise. Failure to comply with regulations could result in enforceable actions, including product seizures, product recalls, withdrawal of clearances or approvals, injunctions, and civil and criminal penalties, any of which could have a material adverse effect on our operating results and reputation. ~~21Our~~ **23Our** products are subject to recall even after receiving FDA or foreign clearance or approval, which would harm our reputation and business. We are subject to medical device reporting regulations that require us to report to the FDA or respective governmental authorities in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to cause or contribute to death or serious injury if the malfunction were to recur. The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacturing. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall would divert managerial and financial resources and could harm our reputation with customers. We cannot assure you that we will not have product recalls in the future or that such recalls would not have a material adverse effect on our business. We have not undertaken any voluntary or mandatory recalls to date. We continue to incur expenses. This area of medical device research is subject to rapid and significant technological changes. Developments and advances in the medical industry by either competitors or other parties can affect our business in either a positive or negative manner. Developments and changes in technology that are favorable to us may significantly advance the potential of our research, while developments and advances in research methods outside of the methods we are using may severely hinder or completely halt our development. We are a small company in terms of employees and technical and research resources. We expect to incur research and development, sales and marketing, and general and administrative expenses. These amounts may increase, and recently have in connection with our efforts to expand our sales force, before any commensurate incremental revenue from these efforts may be obtained and adversely affect our potential profits, and we may lack the liquidity to pay for such expenditures. These factors may also hinder our ability to meet changes in the medical industry as rapidly or effectively as competitors with more resources. Substantial costs could be incurred defending against claims of intellectual property infringement. Other companies, including competitors, may obtain patents or other proprietary intellectual property rights that would limit, interfere with, or otherwise circumscribe our ability to make, use, or sell products. Should there be a successful claim of infringement against us, and if we could not license the alleged infringed technology at a reasonable cost, our business and operating results could be adversely affected. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. The validity and breadth of claims covered in medical technology patents involve complex legal and factual questions for which important legal principles remain unresolved. Any litigation claims against us, independent of their validity, may result in substantial costs and the diversion of resources with no assurance of success. Intellectual property claims could cause us to: ● cease selling, incorporating, or using products that incorporate the challenged intellectual property; ● obtain a license from the holder of the infringed intellectual property right, which may not be available on reasonable terms, if at all; and ● re- design our products excluding the infringed intellectual property, which may not be possible. We may be unable to protect our trademarks, trade

secrets, and other intellectual property rights that are important to our business. We consider our trademarks, trade secrets, and other intellectual property an integral component of our success. We rely on trademark law and trade secret protection and confidentiality agreements with employees, customers, partners, and others to protect our intellectual property. Effective trademark and trade secret protection may not be available in every country in which our products are available. We obtained utility patents on the fluid monitoring system in 2021 and 2018 in the U. S. and in 2020 in Europe. We cannot be certain that we have taken adequate steps to protect our intellectual property, especially in countries where the laws may not protect ~~22our~~ **24our** rights as fully as in the United States. In addition, if our third- party confidentiality agreements are breached, there may not be an adequate remedy available to us. If our trade secrets become publicly known, we may lose competitive advantages. We may fail to protect the privacy, integrity and security of customer information. We possess and process sensitive customer information and Protected Health Information protected by the Health Insurance Portability and Affordability Act (" HIPAA "). While we have taken reasonable and appropriate steps to protect that information, if our security procedures and controls were compromised, it could harm our business, reputation, results of operations, and financial condition and may increase the costs we incur to protect against such information security breaches, such as increased investment in technology, the costs of compliance with healthcare privacy and consumer protection laws. A compromise of our privacy or security procedures could also subject us to liability under certain healthcare privacy laws applicable to us. Other federal and state laws restrict the use and protect the privacy and security of personally identifiable information are, in many cases, are not preempted by HIPAA and may be subject to varying interpretations by the courts and government agencies. These varying interpretations can create complex compliance issues for us and our partners and potentially expose us to additional expense, adverse publicity and liability, any of which could adversely affect our business. There is ongoing concern from privacy advocates, regulators and others regarding data privacy and security issues, and the number of jurisdictions with data privacy and security laws has been increasing. Also, there are ongoing public policy discussions regarding whether the standards for de- identification, anonymization or pseudonymization of health information are sufficient, and the risk of re- identification sufficiently small, to adequately protect patient privacy. We expect that there will continue to be new proposed and amended laws, regulations and industry standards concerning privacy, data protection and information security in the United States, such as the California Consumer Privacy Act (" CCPA "), as amended by the California Privacy Rights Act (" CPRA "), which amendments went into effect on January 1, 2023 ~~,~~ **.** The CCPA creates specific obligations with respect to processing and storing personal information, and the CPRA amendments created a new state agency that is vested with authority to implement and enforce the CCPA. Additionally, a similar law went into effect in Virginia on January 1, 2023, and further US- state comprehensive privacy laws are set to go into effect throughout 2023, including laws in Colorado, Connecticut, and Utah. These laws are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and limited obligations for entities regulated by HIPAA. However, we cannot yet determine the full impact these laws or other such future laws, regulations and standards may have on our current or future business. Any of these laws may broaden their scope in the future, and similar laws have been proposed on both a federal level and in more than half of the states in the U. S. A number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Cyber- attacks and security vulnerabilities could lead to reduced revenue, increased costs, liability claims, or harm to our competitive position. Increased sophistication and activities of perpetrators of cyber- attacks have resulted in an increase in information security risks in recent years. Hackers develop and deploy viruses, worms, and other malicious software programs that attack products and services and gain access to networks and data centers. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The prevalent use of mobile devices also increases the risk of data security incidents. If we experience difficulties maintaining existing systems or implementing new systems, we could incur significant losses due to disruptions in our operations. Additionally, these systems contain valuable proprietary and confidential information and may contain personal data of our customers. While we believe we have taken reasonable steps to protect such data, techniques used to gain unauthorized access to data and systems, disable or degrade service, or sabotage systems, are constantly evolving, and we may be unable to anticipate such techniques or implement adequate preventative measures to avoid unauthorized access or other adverse impacts to such data or our systems. In addition, some of our third- party service providers and partners also collect and / or store our sensitive information and our customers' data on our behalf, and these service providers and partners are subject to similar threats of cyber- attacks and other malicious internet- based activities, which could also expose us to risk of loss, litigation, and potential liability. A security breach could result in disruptions of our internal systems and business applications, harm ~~23to~~ **25to** our competitive position from the compromise of confidential business information, or subject us to liability under laws that protect personal data. Additionally, actual, potential or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third- party experts and consultants. Specifically, as cyber threats continue to evolve, we may be required to expend additional resources to continue to enhance our information security measures and / or to investigate and remediate any information security vulnerabilities. Any of these consequences would adversely affect our revenue and margins. Additionally, although we maintain cybersecurity insurance coverage, we cannot be certain that such coverage will be adequate for data security liabilities actually incurred, will cover any indemnification claims against us relating to any incident, will continue to be available to us on economically reasonable terms, or at all, or that any

insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could have a material adverse effect on our reputation, business, prospects, results of operations and financial condition. We have identified material ~~weaknesses~~ -- **weakness** in our internal controls over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations. 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 a company' s annual or interim financial statements will not be prevented or detected on a timely basis. We identified a material weakness in our internal controls over financial reporting as of December 31, **2024 and** 2023 ~~and 2022~~, related to information technology general controls (" ITGCs ") that were not designed and operating effectively to ~~ensure~~ **IT program and data changes affecting the Company' s financial IT applications and underlying accounting records, are identified, tested, authorized and implemented appropriately to validate that data produced by its relevant IT system** (~~i s~~) ~~appropriate segregation of duties was in place to perform program changes and (ii) the activities of individuals with access to modify data and make program changes~~ were ~~appropriately monitored~~ **complete and accurate** . Business process controls (automated and manual) that are dependent on the affected ITGCs were also deemed ineffective because they could have been adversely impacted. Also as of December 31, 2023, we identified a material weakness in our communications with our independent auditors as it relates to open or pending financial statement adjustments and the timing of decisions to take write- offs. Although the material weaknesses identified above did not result in any material misstatements in our consolidated financial statements for the periods presented and there were no changes to previously released financial results, our management concluded that these control ~~weaknesses~~ -- **weakness** constitute a material weakness and that our internal control was not effective as of December 31, ~~2023~~ **2024** . Our management is committed to take comprehensive actions to remediate the material weakness in internal control over financial reporting. We are in the process of developing and implementing remediation plans to address the material weakness described above. While we are committed to designing and implementing new controls and measures to remediate these material weaknesses, we cannot assure you that the measures will be sufficient to remediate the material weaknesses or avoid the identification of additional material weaknesses in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our consolidated financial statements that could result in a restatement of our financial statements and could cause us to fail to meet our periodic reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock. Expansion of our operations and sales internationally may subject us to additional risks, including risks associated with unexpected events. A component of our growth strategy is to expand our operations and sales internationally. There can be no assurance that we will be able to successfully market, sell, and deliver our products in foreign markets, or that we will be able to successfully expand our international operations. Global operations could cause us to be subject to unexpected, uncontrollable and rapidly changing risks, events, and circumstances. The following factors, among others, could adversely affect our business, financial condition and results of operations: ● difficulties in managing foreign operations and attracting and retaining appropriate levels of senior management and staffing; ● longer cash collection cycles; **26** ● proper compliance with local tax laws which can be complex and may result in unintended adverse tax consequences; ~~24~~ ● difficulties in enforcing agreements through foreign legal systems; ● failure to properly comply with U. S. and foreign laws and regulations applicable to our foreign activities including, without limitation, product approval, healthcare and employment law requirements and the Foreign Corrupt Practices Act; ● fluctuations in exchange rates that may affect product demand and may adversely affect the profitability in U. S. dollars of the products we provide in foreign markets; ● the ability to efficiently repatriate cash to the United States and transfer cash between foreign jurisdictions; and ● changes in general economic conditions or political circumstances in countries where we operate. Our acquisition of other companies could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our operating results. As part of our business strategy, we have made and may in the future acquire or make investments in other companies, solutions or technologies to, among other reasons, expand or enhance our product offerings. In the future, any significant acquisition would require the consent of our lenders. Any failure to receive such consent could delay or prohibit us from acquiring companies that we believe could enhance our business. We may not ultimately strengthen our competitive position or achieve our goals from our recent or any future acquisition, and any acquisitions we complete could be viewed negatively by users, customers, partners or investors. In addition, if we fail to successfully integrate such acquisitions, or the technologies associated with such acquisitions, into our company, the revenues and operating results of the combined company could be adversely affected. For example, in December 2021 we acquired Kestrel Labs, Inc. and we must effectively integrate the personnel, products, technologies and customers and develop and motivate new employees. In addition, we may not be able to successfully retain the customers and key personnel of such acquisitions over the longer term, which could also adversely affect our business. The integration of our recently acquired business or future- acquired business will require significant time and resources, and we may not be able to manage the process successfully. We may not successfully evaluate or utilize the acquired business and accurately forecast the financial impact of the acquisition, including accounting charges. We may have to pay cash, incur debt or issue equity securities to pay for any acquisition, each of which could affect our financial condition or the value of our capital stock. For example, in connection with our acquisition of Kestrel Labs, Inc., we paid an approximate value of $ 30. 5 million, consisting of $ 16. 1 million in cash which was financed through Bank of America N. A. and approximately $ 14. 4 million in shares of our common stock, a portion of which was to be held in escrow. To fund any future acquisition, we may issue equity, which would result in dilution to our stockholders, or incur more debt, which would result in increased fixed obligations and could subject us to additional covenants or other restrictions that would impede our ability to manage our operations. If we are not able to integrate acquired businesses successfully, our business could be harmed. Our inability to successfully integrate our

recent and future acquisitions could impede us from realizing all of the benefits of those acquisitions and could severely weaken our business operations. The integration process may disrupt our business and, if implemented ineffectively, may preclude realization of the full benefits expected by us and could harm our results of operations. In addition, the overall integration of the combining companies may result in unanticipated problems, expenses, liabilities, and competitive responses, and may cause our stock price to decline. The difficulties of integrating an acquisition include, among others: ● unanticipated issues in integration of information, communications, and other systems; ● unanticipated incompatibility of logistics, marketing, and administration methods; ● maintaining employee morale and retaining key employees; **27** ● integrating the business cultures of both companies; ~~25~~ ● preserving important strategic client relationships; ● consolidating corporate and administrative infrastructures and eliminating duplicative operations; and ● coordinating geographically separate organizations. In addition, even if the operations of an acquisition are integrated successfully, we may not realize the full benefits of the acquisition, including the synergies, cost savings, or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frame, or at all. For example, the failure to get regulatory approval to sell certain products of an acquired business may significantly reduce the anticipated benefits of the acquisition and could harm our results of operations, even if we have put in place contingencies for the delivery of closing consideration, such as the escrowed shares initially held back in our acquisition of Kestrel Labs, Inc. Further, acquisitions may also cause us to: ● issue securities that would dilute our current stockholders' ownership percentage; ● use a substantial portion of our cash resources; ● increase our interest expense, leverage, and debt service requirements if we incur additional debt to pay for an acquisition; ● assume liabilities, including environmental liabilities, for which we do not have indemnification from the former owners or have indemnification that may be subject to dispute or concerns regarding the creditworthiness of the former owners; ● record goodwill and non- amortizable intangible assets that are subject to impairment testing on a regular basis and potential impairment charges; ● experience volatility in earnings due to changes in contingent consideration related to acquisition liability estimates; ● incur amortization expenses related to certain intangible assets; ● lose existing or potential contracts as a result of conflict of interest issues; ● incur large and immediate write- offs; or ● become subject to litigation. Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported results of operations. We are required to prepare our financial statements in accordance with generally accepted accounting principles in the United States of America (" GAAP "), which is periodically revised and / or expanded. From time to time, we are required to adopt new or revised accounting standards issued by recognized authoritative bodies, including the Financial Accounting Standards Board (" FASB ") and the SEC. It is possible that future accounting standards we are required to adopt may require additional changes to the current accounting treatment that we apply to our financial statements and may require us to make significant changes to our reporting systems. Such changes could result in a material adverse impact on our business, results of operations and financial condition. The conversion feature of our convertible senior notes, if triggered, may adversely affect our financial condition and operating results. **28** ~~We have outstanding a total of $ 60 million of convertible senior notes. See Note 8: Convertible Senior Notes to the Consolidated Financial Statements included in " Part II, Item 8- Financial Statements and Supplementary Data. " If the conversion feature of any of 26~~