Risk Factors Comparison 2024-03-08 to 2023-03-07 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Annual Report on Form 10- K before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment. Risks Related to Our Business and Industry We have incurred losses in the past and may be unable to achieve or sustain profitability in the future. We have incurred net losses since inception, including net losses of $ ~~37~~ **30** . 2 million and $ ~~31~~ **37** . 2 million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As a result of ongoing losses, as of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~345~~ **376** . ~~9~~ **1** million. We expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand our marketing efforts to increase adoption of our products and expand existing relationships with our customers, to obtain regulatory clearances or approvals for our products in additional countries and for additional indications, and to develop new products or add new features to our existing products. The net losses we incur may fluctuate significantly from quarter to quarter. We will need to generate significant additional revenues to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock. We rely on the sale of our NeuroStar Advanced Therapy System and treatment sessions to generate revenues. We rely on the sale of our NeuroStar Advanced Therapy System and treatment sessions to generate revenues, and we expect to generate substantially all of our revenues in the foreseeable future from sales of these and any related products and services. Because the market for TMS therapy is still developing **and** ~~andcontains~~ -- **contains** a limited number of market participants, sales of our products could be negatively impacted by unfavorable market reactions to our or other TMS devices. If the use of our or other TMS therapies results in serious adverse events, or such products malfunction or are misused, patients and psychiatrists may attribute such negative events to TMS therapy generally, which may adversely affect market adoption of our products. Additionally, if patients undergoing treatment with a NeuroStar Advanced Therapy System perceive the benefits to be inadequate or adverse events too numerous or severe compared to the relevant rates of alternative TMS therapies or pharmaceutical options, it will be difficult to demonstrate the value of our NeuroStar Advanced Therapy System to patients and psychiatrists. As a result, demand for and the use of our NeuroStar Advanced Therapy System may decline or may not increase at the pace or to the levels we expect. Our business **and ability to meet obligations to our customers** may be disrupted and our results of operations **, financial condition, cash flows** and liquidity may be adversely affected by a global pandemic **or epidemic diseases** . Our operations and interactions with healthcare systems, providers and patients expose us to risks associated with public health crises, including epidemics and pandemics. The global impact of COVID- 19, or other global pandemic including corresponding preventative and precautionary measures that we and other businesses, communities and governments may take to mitigate the spread of such disease, may lead to restrictions on, disruptions in, and other related impacts on business and personal activities, which may adversely impact our business and liquidity. ~~In early 2022 and throughout~~ **Throughout** the year ended 2021 **and into early 2022** , we experienced a material impact to revenue particularly with ~~regards~~ - **regard** to U. S. treatment session revenues as a result of the COVID- 19 pandemic. Capital equipment sales and treatment session revenues may continue to be materially impacted by the pandemic as customers defer capital purchase decisions and delay new patient treatment starts. **Further, during the COVID- 19 pandemic, several countries placed significant restrictions on travel within their respective borders, leading to extended business closures in some instances.** The significance of the impact of a global pandemic on our operations depends on numerous evolving factors that we may not be able to accurately predict or effectively respond to, including, among others: ● the effect on global economic activity **, financial markets** and the resulting impact on our customer' s businesses, their credit and liquidity, and their demand for our solutions and services, as well as their ability to pay; ● our ability to deliver and implement our solutions in a timely manner, including as a result of supply chain disruptions and related cost increases; and ● actions taken by U. S., foreign, state, and local governments, suppliers, and individuals in response to the outbreak **(including the extent of travel restrictions and business closures)** . If insurance coverage is unavailable or reimbursement from third- party payors for treatments using our products significantly declines, psychiatrists may be reluctant to use our products. In the United States, sales of our products will depend, in part, on the extent to which the treatment sessions using our products are covered and reimbursed by third- party payors, including private insurers and government healthcare programs. Even if a third- party payor covers a particular treatment that uses our products, the resulting reimbursement rate may not be adequate to cover a provider' s cost to purchase our products or ensure such purchase is profitable for the provider. Further, patients who are treated in- office for a medical condition generally rely on third- party payors to reimburse all or part of the costs associated with ~~the~~ **22the** treatment and may be unwilling to undergo such treatment in the absence of coverage and adequate reimbursement, or due to large annual deductibles associated with certain health insurance plans. Reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that a treatment is neither experimental nor investigational, safe, effective, ~~and~~ medically **reasonable and** ~~21necessary~~ -- **necessary (which may include provision of treatment only in the absence of certain alternatives)** , appropriate for the specific patient, cost- effective, supported by peer- reviewed medical journals and **/ or** included in clinical practice guidelines. In the United States, there is no uniform policy of coverage and reimbursement among third- party payors. Third- party payors often rely upon Medicare coverage policies and payment limitations in setting

their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, coverage ~~and ,~~ reimbursement **and utilization guidelines** for treatments ~~can~~ **may** differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for an in- office treatment is made on a plan- by- plan basis. One payor' s determination to provide coverage for a specific treatment does not assure that other payors will also provide coverage, and adequate reimbursement. In addition, the federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. To contain costs, governmental healthcare programs and third- party payors are increasingly challenging the price, scrutinizing the medical necessity and reviewing the cost- effectiveness of medical treatments. Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets, including Japan, have government- managed healthcare systems that govern reimbursement for psychiatric treatments and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third- party payors outside of the United States are not obtained, international sales of our products may not materialize or grow significantly. The marketability of our products may suffer if the government and third- party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to adequately train psychiatrists and other treatment providers on the safe and appropriate use of our products, we may be unable to achieve our expected growth. There is a learning process involved for treatment providers to become proficient in the use of our products, which requires us to spend considerable time and resources for training. It is critical to the success of our commercialization efforts to train a sufficient number of psychiatrists and to provide them with adequate, ongoing instruction and training in the use of our products. This training process generally requires psychiatrists to review and study product materials, engage in multi- day, hands- on training sessions for up to four hours ~~a~~ **per** day and participate in a multi- day observational period prior to treating patients independently. This training process may also take longer than expected or be more complicated than the psychiatrists or their personnel are comfortable with and may therefore affect our ability to increase sales. Convincing psychiatrists to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts. Our revenue has been concentrated among a small number of customers, and if we lose any of these customers and fail to replace them, our revenue may decrease substantially. A significant amount of our revenue is derived from a limited number of customers. Any material non- payment or non- performance by one of these customers, a significant downturn or deterioration in the business or financial condition of any of these customers, or any other event significantly negatively impacting a ~~contractual~~ **23contractual** relationship with one of these customers could adversely affect our financial condition and results of operations. ~~22Customers~~ -- **Customers** and their patients may be slow to adopt and use TMS therapies. TMS therapy is an emerging treatment option for patients suffering from MDD. As a result, customer and patient awareness of TMS therapy as a treatment option for MDD, and experience with TMS therapies, is limited. Our success depends in large part on our ability to educate and train customers and patients, and successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our NeuroStar Advanced Therapy System. We have been engaging in an active marketing campaign to raise awareness of our NeuroStar Advanced Therapy System and its benefits among customers, but we cannot assure you that these efforts will be successful or that they will not prove to be cost-prohibitive. Some customers may also find the initial patient set up and the subsequent procedures for future treatment sessions to be difficult or complicated, or could be wary of the initial investment required for the purchase of the NeuroStar Advanced Therapy System, which may impact their decision to purchase or use the NeuroStar Advanced Therapy System as part of their practice. Similarly, customers may find it difficult to hire additional staff, allocate sufficient space or operationalize our NeuroStar Advanced Therapy System, which could slow its adoption. In addition, customers may not derive sufficient cash flow from using the NeuroStar Advanced Therapy Systems due to their own practice economics or otherwise. Failure to achieve economic benefits from the purchase or use of the NeuroStar Advanced Therapy System would adversely affect our customers' purchase of treatment sessions. These factors could also reduce the number of procedures performed using our NeuroStar Advanced Therapy System, and if we do not facilitate the utilization of our products by our customers, our revenues and results of operations could be harmed. Our success depends upon patient satisfaction with the effectiveness of our NeuroStar Advanced Therapy System. In order to generate repeat and referral business, patients must be satisfied with the effectiveness of our NeuroStar Advanced Therapy System. Clinical studies demonstrate that, in order to be effective, our products must be used for a period of four to six weeks, and require a patient to return to a psychiatrist' s office five days a week during that period in order to receive the recommended course of treatment. Since patients who achieve response or remission using our therapy will obtain these results gradually over this treatment period, their perception of their results may vary depending on their compliance with the prescribed treatment course. We train our customers to select the appropriate patient candidates for treatment using the NeuroStar Advanced Therapy System, explain to their patients the time- period over which the results from a treatment course can be expected to occur, and measure the success of treatments using medical guidelines. However, our customers may not select appropriate patient candidates for NeuroStar Advanced Therapy **System** treatment, which may produce results that may not meet patients' expectations. In addition, the efficacy of treatment is dependent on proper patient set up at the initial treatment session and duplication of that set up at future treatment sessions. To the extent customers do not make the proper measurements for a specific patient or use the same procedures at each treatment session, it could result in variability of the treatment efficacy and results for the patient. If patients are not satisfied with the results of our NeuroStar Advanced Therapy System, our reputation and future sales will suffer. We operate in a very competitive environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected. Our currently marketed products are, and any future products we develop and commercialize will be, subject to intense competition. The industry in which we operate is subject to rapid change and is highly sensitive to the introduction of new

products or other market activities of current or new industry participants. Our ability to ~~compete~~ **24compete** successfully will depend on our ability to develop products that reach the market in a timely manner, to receive adequate coverage and reimbursement from third- party payors, and to successfully demonstrate to psychiatrists and patients the merits of our products compared to those of our competitors. If we are not ~~23successful~~ **successful** in convincing others of the merits of our products, including in comparison to those of our competitors, or educating them on the use of our products, they may not use our products or use them effectively and we may be unable to increase our sales. We have competitors that sell other forms of TMS therapy, including Brainsway, Magstim, MagVenture, CloudTMS and Nexstim, that compete directly with the NeuroStar Advanced Therapy System. Competing TMS therapy companies have developed and may develop additional treatments that can be administered for shorter time periods or for indications outside of MDD, or may develop treatments that have improved efficacy when compared to our products or that require a less significant investment of resources from psychiatrists. We also face competition from pharmaceutical and other companies that develop competitive products, such as antidepressant medications. Our commercial opportunity could be reduced or eliminated if these competitors develop and commercialize antidepressant medications or other treatments that are safer, more convenient or more effective than the NeuroStar Advanced Therapy System. At any time, these and other potential market entrants may develop treatment alternatives that may render our products uncompetitive. In addition, our competitors may have more established distribution networks than we do, or may be acquired by enterprises that have more established distribution networks than we do. Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar products. We also compete with our competitors in acquiring technologies and technology licenses complementary to our products or advantageous to our business. In addition, we compete with our competitors to engage the services of independent distributors outside the United States, both those presently working with us and those with whom we hope to work as we expand. We may face difficulties encountered by companies in new and evolving markets. In assessing our prospects, you must consider the risks and difficulties frequently encountered by companies in new and evolving markets. These risks include our ability to: ● manage rapidly changing and expanding operations; ● increase awareness of our brand and strengthen customer loyalty; ● successfully execute our business and marketing strategy; ● respond effectively to competitive pressures and developments; ● continue to develop and enhance our products and products in development; ● obtain regulatory clearance or approval to commercialize new products and enhance our existing products; ● refrain from infringing on the intellectual property rights of others, and maintaining appropriate legal policies and procedures; ● expand our presence in existing and commence operations in new international markets; and ● attract, retain and motivate qualified personnel. ~~24If~~ **25If** we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenues to achieve or sustain profitability. Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team as well as our field sales personnel in the United States and our independent third- party distributors outside of the United States. If our employees or our independent distributors fail to adequately promote, market and sell our products, our sales could significantly decrease. If we launch new products, expand our product offerings to new indications or increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled employees, and distributors with significant technical knowledge in various areas. Further, most of the salespersons we recently hired have technical expertise from other industries but no experience within our specific industry. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, new hires fail to successfully transition to our industry, or we experience high turnover in our sales force in the future, new hires may not become as productive as may be necessary to maintain or increase our sales. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may be unable to effectively commercialize our products. The loss of any member of our senior management or our inability to attract and retain highly skilled executives, salespeople, product development and other personnel could negatively impact our business. Our success depends on the skills, experience and performance of the members of our senior management team. The individual and collective efforts of these employees will be important as we continue to develop our products and as we expand our commercial activities. We believe that it is challenging to identify individuals with the requisite skills to serve in many of our key positions, and the loss or incapacity of existing members of our executive management team could negatively impact our operations. We did not maintain key ~~man~~ **person** life insurance on any of our employees in ~~2022~~ **2023 (other than our Chief Executive Officer, on whom we maintained a $ 1, 000, 000 key person life insurance policy)** and do not expect **to** in the future. Our Chief Executive Officer' s employment agreement does not guarantee our retention of our Chief Executive Officer for any period of time. Our commercial, supply chain and research and development programs and operations depend on our ability to attract and retain highly skilled managers, salespeople and product development and customer training personnel. We may be unable to attract or retain qualified managers, salespeople or product development and customer training personnel in the future due to the competition for qualified personnel in the medical treatment and device fields, as well as other fields. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting and retention difficulties can limit our ability to support our commercial, supply chain and research and development programs. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for key employees could harm our business. Our long- term growth depends on our ability to commercialize our approved products for current and future indications and to develop and commercialize additional products through our research and development efforts. If we fail to do so we may be unable to compete effectively. In order to increase our future revenues, we must successfully enhance our existing product offerings and introduce new products in response to changing customer demands and competitive pressures and technologies. Our industry is characterized by intense competition,

including from lower- cost competitors, rapid technological changes, new product introductions and enhancements and evolving industry standards. We also face competition from pharmaceutical companies, including large pharmaceutical companies with ~~greater~~ **26greater** capital. Our business prospects depend in part on our ability to develop and commercialize new products and applications for our technology, including in new markets that develop as a result of ~~25technological~~ -- **technological** , pharmaceutical and scientific advances, while improving the performance and cost- effectiveness of our products. New pharmaceutical products, technologies, techniques or other products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as psychiatrist practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost- effective basis. We might be unable to successfully further commercialize or develop or obtain regulatory clearances or approvals to market new products or our existing products for additional indications. Future products, even if cleared, might not be accepted by psychiatrists or the third- party payors who reimburse for the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on numerous additional factors, including our ability to: ● properly identify and anticipate clinician and patient needs; ● demonstrate the benefits associated with the use or our products when compared to the products and devices of our competitors; ● 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; and ● obtain the necessary regulatory clearances or approvals for new products or product enhancements. If we do not develop and obtain regulatory clearances or approvals for new products or indications 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 develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features. Nevertheless, we must carefully manage our introduction of new products. If potential customers believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have limited experience in managing product transitions. We rely on single- source suppliers for some components used in our NeuroStar Advanced Therapy System and on a single manufacturer for the assembly of our NeuroStar Advanced Therapy System, and we may be unable to find replacements or immediately transition to alternative parties for these components. We rely on single- source suppliers for some components used in our NeuroStar Advanced Therapy System, and we do not have long- term supply contracts with these suppliers. Furthermore, we rely on a single manufacturer for the assembly of the mobile console and patient positioning system used in our NeuroStar Advanced Therapy System. For us to be successful, our suppliers and contract manufacturer must be able to ~~provide~~ **27provide** us with components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. While these suppliers ~~26have~~ -- **have** generally met our demand requirements on a timely basis in the past, their ability and willingness to continue to do so going forward may be limited for several reasons, including our lack of long- term agreements with those suppliers, our relative importance as a customer of those suppliers, or, as applicable, their ability to produce the components for or provide assembly services to manufacture our NeuroStar Advanced Therapy System. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components or manufactured products, if we cannot obtain an acceptable substitute. Any transition to a new supplier or contract manufacturer could be time- consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our NeuroStar Advanced Therapy System or could require that we modify its design. If we are required to change our contract manufacturer, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. If the change in manufacturer results in a significant change to any product, a new 510 (k) clearance from the FDA or similar non- U. S. regulatory authorization may be necessary before we implement the change, which could cause a substantial delay. We cannot assure you that we will be able to identify and engage alternative suppliers or contract manufacturers on similar terms or without delay. Furthermore, our contract manufacturer could require us to move to a different production facility. The occurrence of any of these events could harm our ability to meet the demand for our NeuroStar Advanced Therapy System in a timely and cost- effective manner. **During 2023, we transitioned to a new contract manufacturer for our console in a planned process.** We may be unable to achieve or manage our anticipated growth effectively, which could make it difficult to execute our business strategy. We have a relatively short history of operating as a commercial company and our growth rate may be volatile. For example ~~, our revenues decreased from $ 62. 6 million~~ for ~~the year ended December 31, 2019 to $ 49. 2 million for the year ended December 31, 2020~~ **2023** , **2022** and ~~our revenues increased from $ 55. 3 million for the year ended December 31,~~ 2021 **our growth rate was 9 %** ~~to $ 65. 2 million for the year ended December 31~~ , ~~2022~~ **18 % and 12 % respectively** . We intend to grow our business operations and may experience periods of rapid growth and expansion. This anticipated growth could create a strain on our organizational, administrative and operational infrastructure, including our supply chain operations, quality control, technical support and customer service, sales force management and general and financial administration. We may be unable to maintain the quality, or delivery timelines, of our products or customer service or satisfy customer demand if our business grows too rapidly. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, and our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business

processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business. As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for our supply chain, customer service, training and education personnel, billing, accounting reporting and general process improvements and expand our internal quality assurance program, among other things. Because our products require us to devote significant resources to training our customers on the use, and educating our customers on the benefits, of our products, we will be required to expand these personnel as we increase our sales efforts. We may not successfully implement these increases in scale or the expansion of our personnel, which could harm our business. We rely on a network of third- party distributors to market and distribute our products internationally, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales. We rely on a network of third- party distributors to market and distribute our products in international markets. We currently sell our products in five countries outside of the United States and plan to market and sell our ~~products~~ **28products** through our exclusive distribution agreement in Japan once we attain reimbursement approval. We ~~27are~~ -- **are** assessing the opportunity to continue expanding into other international markets. We may face significant challenges and risks in managing a geographically dispersed distribution network. We have limited ability to control any third- party distributors. Our distributors may be unable to successfully market and sell our products and may not devote sufficient time and resources to support the marketing, sales, education and training efforts that we believe enable the products to develop, achieve or sustain market acceptance. Additionally, in some international jurisdictions, we rely on our distributors to manage the regulatory process, while complying with all applicable rules and regulations, and we are dependent on their ability to do so effectively. In addition, if a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals and to train new personnel to market our products, and our ability to sell those systems in the region formerly serviced by such terminated distributor could be harmed. Any of these factors could reduce our revenues from affected markets, increase our costs in those markets or damage our reputation. In addition, if an independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent that distributor from helping competitors solicit business from our existing customers, which could further adversely affect our sales. As a result of our reliance on third- party distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third- party error and other issues. If the services of any of these third- party distributors become unsatisfactory, we may experience delays in meeting our customers' demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose potential customers. We face risks associated with our international business. We currently market and sell our products outside of the United States, including in Japan, and plan to market and sell our products through our exclusive distribution agreement in Japan. Once we attain satisfactory reimbursement approval, we expect that sales of our NeuroStar Advanced Therapy System in Japan will increase. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U. S. and other foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non- compliance. We expect our international activities will be dynamic over the foreseeable future as we continue to pursue opportunities in international markets. Our international business operations are subject to a variety of risks, including: ● difficulties in staffing and managing foreign and geographically dispersed operations, to the extent we establish non- U. S. operations; ● attaining reimbursement under differing and multiple payor reimbursement regimes, government payors or patient self- pay systems; ● difficulties in determining and creating the proper sales pathway in new, international markets; ● compliance with various U. S. and international laws, including export control laws and the U. S. Foreign Corrupt Practices Act of 1977, (the " FCPA "), and anti- money laundering laws; ● differing regulatory requirements for obtaining clearances or approvals to market our products; ● changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States; **29** ● tariffs and trade barriers, export regulations, sanctions and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets; ~~28~~ ● potential adverse tax consequences, including imposition of limitations on or increases of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures; ● imposition of differing labor laws and standards; ● armed conflicts or economic, political, health (including pandemic diseases ~~such as COVID- 19 from coronavirus~~) or social instability in foreign countries and regions; ● fluctuations in foreign currency exchange rates; ● an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; ● availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us; and ● conducting post- market surveillance on product performance. We are assessing the opportunity to expand into other international markets. However, our expansion plans may not be realized, or if realized, may not be successful. We expect each market to have particular regulatory hurdles to overcome, and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business. Our employees, consultants, distributors and other commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, consultants, distributors and other commercial partners may engage in inappropriate, fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other U. S. healthcare regulators, as well as non- U. S. regulators, including by violating laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive

practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, distributors and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. These risks may be more pronounced, and we may find that the processes and policies we have implemented are not effective at preventing misconduct. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become 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 the curtailment of our operations. Whether or not we are successful in defending against such ~~actions~~ **30actions** or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations. ~~29We~~ **We** rely in part on third parties to conduct our clinical trials. If these third parties fail to perform their duties on time or as expected, we may not be able to obtain regulatory approval for additional indications that we may seek for the NeuroStar Advanced Therapy System. Our clinical trials are managed by our own staff and personnel, but we rely in part upon certain third parties, including clinical trial sites, medical institutions, clinical research organizations, (" ~~CRO~~ **CROs** " ~~s~~), and private practices, for, among other things, site monitoring, statistical work and electronic data capture in our clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocols, and legal, regulatory and scientific standards, including current good clinical practices, (" ~~eGCP~~ **CGCPs** " ~~s~~), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for clinical trials. If we or any such third parties fail to comply with applicable ~~eGCPs~~ **CGCPs** , the clinical data generated in such trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a marketing application for any particular indication. In addition, if such third parties do not devote sufficient time and resources to our clinical trials or otherwise carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they assist in obtaining is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates in a specified indication. If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage. Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for the treatment of MDD. Our treatments are designed for patients who suffer from significant neurohealth disorders, and these patients are more likely to experience significant adverse health outcomes, which could increase the risk of product liability lawsuits. Furthermore, if psychiatrists are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product- related risks or product- related information resulted in an unsafe condition or injury to patients. Regardless of the merit or eventual outcome, product liability claims may result in: ● decreased demand for our products; ● injury to our reputation; ● significant litigation costs; ● substantial monetary awards to or costly settlements with patients; ● product recalls; ● material defense costs; ● loss of revenues; ● the inability to commercialize new products or product candidates; ~~and~~ **and31** ● diversion of management attention from pursuing our business strategy. ~~30Our~~ -- **Our** existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers. Our insurance policies protect us only from some business risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, cybersecurity liability, employee benefits liability, property, umbrella, workers' compensation, products and clinical trial liability and directors' and officers' insurance. We do not know, however, if these policies will provide us with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. We bear the risk of warranty claims on our products. We bear the risk of warranty claims on the products we supply for one year from the date of delivery. There can be no assurance that we will not face increased claims in the future. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third- party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. We could be negatively impacted by violations of applicable anti- corruption laws or violations of our internal policies designed to ensure ethical business practices. We operate in a number of countries throughout the world, including in countries that do not have as strong a commitment to anti- corruption and ethical behavior as is required by U. S. laws and by our corporate policies. We are subject to the risk that we, our U. S. employees or any future employees or consultants located in other jurisdictions or any third parties such as our distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti- corruption laws in any jurisdiction in which we conduct business, including the

FCPA. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of " off books " slush funds from which such improper payments can be made. We will face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. We have implemented company policies relating to compliance with the FCPA and similar laws. However, such policies may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors state our expectations for our distributors' compliance with U. S. laws, including the FCPA, and provide us with various remedies upon any non- ~~compliance~~ **32compliance** , including the ability to terminate the agreement, our distributors may not comply with U. S. laws, including the FCPA. ~~31Any --~~ **Any** violation of the FCPA or any similar anti- corruption law or regulation could result in substantial fines, sanctions, civil and / or criminal penalties and curtailment of operations in certain jurisdictions and might harm our business, financial condition or results of operations. If we experience significant disruptions in our information technology systems, our business may be adversely affected. We depend on our information technology systems for the efficient functioning of our business, including for our TrakStar system and accounting, data storage, compliance, purchasing and inventory management. We do not have redundant systems at this time. While we will attempt to mitigate interruptions, we may experience difficulties in implementing upgrades to our information technology systems, which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to provide customers with data on patient outcomes, track the usage of our products, timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to access patient data or use our products for treatments. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows. Currently we carry business interruption coverage to mitigate any potential losses, but we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business. Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis. Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point- to- point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis. Security and privacy breaches may expose us to liability and harm our reputation and business. As part of our business we receive and process information about our customers, partners and their patients, including PHI, and we may store or contract with third parties to store our customers' data, including PHI. PHI, a subset of individually identifiable information, is regulated at the federal level by HIPAA, as amended by HITECH, and by various laws at the state level, as more fully described below. We are required to safeguard PHI in accordance with HIPAA and, as a business associate, we are also directly liable for compliance with HIPAA. The security measures we have implemented relating to our NeuroStar Advanced Therapy System and TrakStar database, specifically, and our operations, generally, may not prevent security breaches that could ~~harm~~ **33harm** our business. Advances in computer capabilities, inadequate technology or facility security measures or other factors may result in a compromise or breach of our systems and the data and PHI we store and process. Our security measures **have been and** may **in the future** be breached as a result of actions by third parties or employee error or ~~32malfeasance --~~ **malfeasance** . A party who is able to circumvent our security measures or exploit inadequacies in our security measures, could, among other things, misappropriate proprietary information, including information about our customers and their patients, cause the loss or disclosure of some or all of this information, cause interruptions in our or our customers' operations or expose our customers to computer viruses or other disruptions or vulnerabilities. Any compromise of our systems or the data we store or process could implicate reporting requirements under HIPAA, result in a loss of confidence in the security of our software, damage our reputation, disrupt our business, lead to legal liability and adversely affect our results of operations. Moreover, a compromise of our systems could remain undetected for an extended period of time, exacerbating the impact of that compromise. Actual or perceived vulnerabilities may lead to claims against us by our customers, their patients or other third parties, including the federal and state governments. While our customer agreements typically contain provisions that seek to limit our liability, there is no assurance these provisions will be enforceable and effective under applicable law. In addition, the cost and operational consequences of implementing further data protection measures could be significant. Employment litigation and unfavorable publicity could negatively affect our future business. Employees may, from time to time, bring lawsuits against us or make public claims about us regarding injury, creating a hostile workplace, discrimination, wage and hour,

sexual harassment and other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Companies that have faced employment or harassment related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their sales. If we were to face any employment related claims or allegations, our business could be negatively affected. The 2017 comprehensive tax reform law could adversely affect our business and financial condition. On December 22, 2017, President Trump signed into law new legislation, (Pub. L. 115- 97), commonly referred to as the Tax Cuts and Jobs Act of 2017, (the " TCJA "), which significantly revised the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contained significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, limitation of the tax deduction for interest expense to 30 % of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 % of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U. S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the TCJA. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock. Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. We are subject to taxation in numerous U. S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to ~~state~~ **34state** , the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or ~~33our~~ -- **our** current expectations and may result in tax obligations in excess of amounts accrued in our financial statements. Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control. A major earthquake, fire or other disaster, such as a major flood, seasonal storms, global pandemic (such as COVID- 19), or terrorist attack affecting our facilities, or those of our third- party manufacturers or suppliers, could significantly disrupt our or their operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our third- party manufacturers or suppliers' damaged manufacturing facilities. These delays could be lengthy and costly. If any of our manufacturers', suppliers' or customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our or their facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak a pandemic (such as COVID- 19) could have a negative effect on our operations. ~~Epidemic diseases could negatively affect various aspects of our business, make it more difficult to meet our obligations to our customers, and could result in reduced demand from our customers. These could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Our business could be adversely affected by the effects of a widespread outbreak of contagious disease, including the recent outbreak of a respiratory illness known as COVID-19 caused by coronavirus. In an effort to halt the outbreak of COVID-19, the Chinese government and the governments of other impacted countries, such as Italy and the Republic of Korea, have placed significant restrictions on travel within their respective borders, leading to extended business closures in some instances. These travel restrictions and business closures could adversely impact our operations in Japan, including our ability to sell or distribute our products, as well as cause temporary or long- term closures of the offices and facilities of our suppliers and customers. Any disruption of our suppliers in China or customers in Japan could impact our global sales and operating results. We cannot at this time accurately predict what effects these conditions will have on our operations due to uncertainties relating to the ultimate geographic spread of the virus, the incidence and severity of the disease, the duration of the outbreak, and the length of the travel restrictions and business closures imposed by governments of impacted countries. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products and likely impact our operating results.~~ We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could harm our business. Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products ~~34or~~ **or** expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including: ● difficulty assimilating or integrating acquired or licensed technologies, products or business operations; ● issues

maintaining uniform standards, procedures, controls and policies; ● unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write- offs of intangible assets or goodwill; ● diversion of management' s attention from our core business and disruption of ongoing operations; ● adverse effects on existing business relationships with suppliers, distributors and customers; ● risks associated with entering new markets in which we have limited or no experience; ● potential losses related to investments in other companies; **35** ● potential loss of key employees of the acquired businesses; and ● increased legal and accounting compliance costs. We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries. To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock or other equity- linked securities as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our stock as consideration. Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States. Generally accepted accounting principles in the United States, (" U. S. GAAP "), are subject to interpretation by the Financial Accounting Standards Board, (" FASB "), or SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results and could affect the reporting of transactions completed before the announcement of a change. Refer to " Note 4. Recent Accounting Pronouncements " in our audited financial statements and related notes thereto included elsewhere in this Annual Report on Form 10- K. ~~35Our~~ -- **Our** sales volumes and our results of operations may fluctuate over the course of the year. We have experienced and may continue to experience meaningful variability in our sales and gross profit among fiscal quarters. In the first quarter, our results can be impacted by the resetting of annual U. S. patient healthcare insurance plan deductibles, which may cause delays in patients seeking NeuroStar Advanced Therapy **System** treatments. Historically, we have seen a sequential decline in third quarter revenues, which we believe is attributable to summer vacation plans of psychiatrists and patients. In addition, the fourth quarter has consistently been a strong revenue quarter on a sequential basis primarily due to U. S. psychiatrists' historical timing for capital expenditures and patients' needs to exhaust remaining balances in flexible spending accounts. Additional factors that we expect may contribute to variability in our sales and gross profit over the course of the year include: ● the growth or decline of our installed system base; ● the unpredictability of future sales by our international distributors, including through our exclusive distributor in Japan; ● the demand for, and pricing of, our products and the products of our competitors; **36** ● the timing of or failure to obtain regulatory clearances or approvals for other products, indications or treatments; or ● the costs, benefits and timing of new product introductions. Risks Related to Intellectual PropertyIf we are not able to obtain and enforce patent protection for our technologies, products, or product candidates, development and commercialization of our products and product candidates may be adversely affected. Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. We have applied, and we intend to continue applying, for patents covering aspects of our technologies that we deem appropriate. However, the patent process is expensive and time consuming, and we may not be able to apply for patents on certain aspects of our current or future products and other technologies in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. We cannot offer any assurances about which, if any, of our patent applications will issue or whether any of our issued patents will be found invalid and unenforceable or will be threatened by third parties. Any patent applications we file may be challenged and may not result in issued patents or may be invalidated or narrowed in scope after they are issued. We also cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect and provide exclusivity for our products, any additional features we develop for our products or any new products. Other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. Any successful opposition to these patents or any other patents owned by or, if applicable in the future, ~~36licensed~~ -- **licensed** to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop. Since patent applications in the US and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our technologies, products, or product candidates. Furthermore, an interference proceeding can be provoked by a third party or instituted by the United States Patent and Trademark Office, (the " USPTO "), to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Once granted, patents may remain open to opposition, interference, re- examination, post- grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after

allowance or grant, during which time third parties can raise objections against such initial grant. Proceedings challenging our patents, which may continue for a protracted period of time, could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products. ~~Furthermore~~ **37Furthermore** , though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for alternative and possibly more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel. The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: ● any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our products; ● any of our pending patent applications or those of our licensors may issue as patents; ~~37~~ ● others will not or may not be able to make, use, offer to sell, or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license; ● we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire; ● we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license; ● we or our licensors were the first to file patent applications for these inventions; ● others will not develop similar or alternative technologies that do not infringe the patents we own or license; ● any of the patents we own or license will be found to ultimately be valid and enforceable; ● any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable products or will provide us with any competitive advantages; **38** ● a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed; ● we may develop or in- license additional proprietary technologies that are patentable; ● the patents of others will not have an adverse effect on our business; ● our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● we will develop additional proprietary technologies or products that are separately patentable; or ● our commercial activities or products will not infringe upon the patents of others. Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our inability to effectively protect our proprietary technologies could harm our competitive position. Although our competitors have utilized and are expected to continue utilizing technologies similar to ours, our success will depend upon our ability to protect and continue to develop proprietary technologies and products and to defend any advantages afforded to us relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our technologies and thereby erode any competitive advantages we may have. For example, patents for our core technology will begin to expire in the United States in 2024, and our patents outside of the United States are expected to remain in effect until between ~~382024~~ -- **2024** and 2035. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We have agreements with our employees and selected consultants that obligate them to assign their inventions to us. If the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, including by refusing or being unavailable to sign assignments, oaths, declarations or other documents, we may not have adequate remedies for any such breach or violation, and we could lose our rights in inventions through such breaches or violations. Furthermore, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. The lives of our patents may not be sufficient to effectively protect our products and business. Patents have a limited lifespan. In the US, the natural expiration of a **utility** patent is generally 20 years after its first effective ~~non- provisional~~ filing date **. The natural expiration of a design**

patent is generally 14 years after the grant of the design patent for design patent applications filed before May 13, 2014, and the natural expiration of a design patent is generally 15 years after the grant of the design patent for design patent applications that are filed on or after May 13, 2015 . Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, or product candidates are obtained, once the patent life has expired, we may be open to competition. Patents covering some of our core ~~technology~~ **39technology** have expired or will expire within the next five years. In addition, although upon issuance in the United States a patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our technologies, products, and product candidates, our business and results of operations will be adversely affected. Litigation or other proceedings or third- party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products. Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U. S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U. S. applications that will not be filed outside the U. S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant ~~39may~~ -- **may** be incorrect, which may negatively impact our ability to develop and market our products or product candidates. Significant litigation regarding patent rights occurs in our industry. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non- practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management' s attention being diverted to patent litigation. We may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post- grant proceedings such ~~as~~ **40as** review, reexamination, interference or derivation proceedings before the **USPTO** ~~U. S. Patent and Trademark Office~~ and challenges in U. S. District Court. Patents may be subjected to opposition, post- grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time- consuming, regardless of the merit of the claims, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following: ● stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property; ● lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; ● incur significant legal expenses; ● pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, including enhanced damages if we are found to have willfully infringed or misappropriated such rights; ● pay the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; ● redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and ● attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core ~~40business~~ -- **business** and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and / or substantial royalties and could be prevented

from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights ~~of~~ **41of** third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us. In addition, we generally indemnify our customers and international distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. In addition to patent protection, we also rely upon copyright and trade secret protection, unpatented know- how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect through non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third- party ~~41contractors --~~ **contractors** and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed. We may be unable to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending ~~intellectual~~ **42intellectual** property rights in certain foreign jurisdictions. These challenges can be caused by the absence or inconsistency of the application of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop infringement of our foreign patents, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and

foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products, and product candidates. While we will endeavor to try to protect our technologies, products, and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time- consuming, expensive and sometimes unpredictable. Third parties may assert ownership or commercial rights to inventions we develop. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property, including studies we commission or reports on the efficacy of our products. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position. ~~42Third~~ -- **Third** parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. ~~Changes~~ **43Changes** in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. Our patent rights may be affected by developments or uncertainty in the patent statute, patent case law or USPTO rules and regulations. There are a number of recent changes to the patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the United States has enacted and is currently implementing the America Invents Act of 2011, a wide- ranging patent reform legislation. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. As an example, the first to file provisions, which became effective March 2013, mean that the party that is first to file in the United States generally is awarded the patent rights, regardless of who invented first. This could have a negative impact on some of our IP and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents. Further, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the **USPTO** ~~U. S. Patent and Trademark Office~~ , the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the US in several stages over the lifetime of the patents and / or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we in- license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. ~~43If~~ **If** we fail to comply with our obligations under license or technology agreements with third parties, we may be required to pay damages and we could lose license rights that are critical to our business. We license certain intellectual property, and in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various payment obligations on us. If we fail to comply with any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor could cause us to lose valuable rights, and could prevent us from distributing our products, or inhibit our ability to commercialize future products. Our business could suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. ~~Any~~ **44Any** collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products. Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that: ● collaborators have significant discretion in determining the efforts and resources that

they will apply to collaborations; ● collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; ● collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; ● a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities; ● we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; ● collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; ● disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources; ● collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products; ● collaborators may own or co- own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; ~~and~~44 -- **and** ● a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive. Our trademarks or trade names may be determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the ~~USPTO~~ **45USPTO** and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Risks Related to Government RegulationOur products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business. We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA, FTC, and their foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post- market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties. ~~45We~~ **We** may not receive the necessary regulatory clearances or approvals to market our future products or other proposed indications for our products in the future, and failure to timely obtain necessary clearances or approvals for such future products or indications would adversely affect our ability to grow our business. An element of our strategy is to continue to upgrade our products, add new enhancements and features and expand clearance or approval of our current products to include new indications. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510 (k) of the Federal Food, Drug and Cosmetic Act or approval of a premarket approval application (PMA) from the FDA, unless an exemption applies. In the 510 (k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is " substantially equivalent " to a legally- marketed " predicate " device, which includes a device that has been previously cleared through the 510 (k) process, a device that was legally marketed prior to May 28, 1976 (pre- amendments device), a device that was originally on the U. S. market pursuant to an approved PMA and later down- classified, or a 510 (k)- exempt device. To be " substantially equivalent, " the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial ~~equivalence~~ **46equivalence** . In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre- clinical, clinical trial, manufacturing and labeling data. Our ability to successfully obtain clearance for

any new indications will be dependent on us submitting data as to the successful completion of clinical trials evidencing safety and efficacy. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life- supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the de novo classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down- classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down- classification request, the applicant will then receive authorization to market the device. This device type can then be used as a predicate device for future 510 (k) submissions. We initially received marketing authorization of our device through the de novo classification process, and we have made changes to our system through subsequent 510 (k) clearances. Competitors may seek 510 (k) clearance of similar products with similar indications and use our de novo classification as a predicate device in their submission. The process of obtaining regulatory clearances or approvals, or completing the de novo classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre- market reviews on a timely basis, if at all. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: we may be unable to demonstrate to the FDA' s satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use; the data from our pre- clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and the manufacturing process or facilities we use may not meet applicable requirements. The FDA may also, instead of accepting a 510 (k) submission, require us to submit a PMA, which is typically a much more complex, lengthy, and burdensome application than a 510 (k) submission. To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. In some cases, such studies may be requested for a 510 (k) as well. We may not be able to meet the requirements to obtain 510 (k) clearance or PMA ~~approval~~ (or a de novo classification request), in which case the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended uses of our products as a condition to a 510 (k) clearance or PMA ~~approval~~. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approval of new products we develop, any limitations imposed by the FDA on new product use or the costs of obtaining FDA ~~46clearance~~ -- **clearance** or approvals could have a material adverse effect on our business, financial condition, and results of operations. Even if granted, a 510 (k) clearance, de novo classification, or PMA ~~approval~~ imposes substantial restrictions on how our devices may be marketed or sold, and the FDA continues to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with the FDA' s Quality System Regulation (QSR). In addition, manufacturers must register their manufacturing facilities, list the products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export restrictions. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions: untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; customer notifications or repair, replacement, refunds, recalls, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production; refusing or delaying requests for 510 (k) marketing clearance or PMA ~~approvals~~ of new products or modified products; withdrawing 510 (k) marketing clearances or ~~PMA~~ **PMAs** ~~approvals~~ that have already been granted; refusing to provide Certificates for Foreign Government; refusing to grant export approval for our products; or pursuing criminal prosecution. Any of these sanctions could impair our ability to produce or commercialize our products in a cost- effective and timely manner in ~~order~~ **47order** to meet our customers' demands and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other regulatory compliance costs or take other actions that may have a negative impact on our sales and our ability to generate profits. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently marketed products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510 (k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad, especially with a new administration that may have different policy priorities than the previous one. In order to sell our products in member countries of the European Economic Area, or (EEA) or in countries that also rely on the CE Mark outside the EEA, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93 / 42 / EEC), and with the Medical Device Regulation (Regulation 2017 / 745). Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low- risk medical devices (Class I non-sterile, non- measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self- assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our

devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and ~~47performance~~ -- **performance** of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our surgical systems, which would prevent us from selling them within the EEA and may have an impact on our marketing authorization in other countries. We or our distributors will also need to obtain or retain regulatory approval in other foreign jurisdictions in which we plan to or currently do market and sell our products, and we or they may not obtain such approvals as necessary to commercialize our products in those territories. Regulatory marketing authorizations in these foreign jurisdictions typically require device testing, conformance to classification requirements, pre- market requests to authorize commercialization, and in some cases inspections. Modifications to our products may require new 510 (k) clearances. de novo classification, or ~~PMA~~ **PMAs** ~~approvals~~ , and may require us to cease marketing or recall the modified products until clearances or approvals are obtained. Any modification to a 510 (k)- cleared product that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510 (k) clearance ~~or~~ **48or** de novo classification, or, possibly, approval of a PMA. Modifications to products that have been approved through the PMA process generally require premarket FDA approval. Similarly, certain modifications made to products cleared through a 510 (k) or authorized through the de novo classification process may require a new 510 (k) clearance. Each of the PMA, de novo classification, and the 510 (k) clearance processes can be expensive, lengthy, and uncertain. The FDA' s 510 (k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510 (k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort, and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory authorizations could harm our business. Furthermore, even if we are granted regulatory authorizations, they may include significant limitations on the indicated uses for the device, which may limit the market for the device. Any modifications to our existing products may require new 510 (k) clearance; however, future modifications may be subject to the substantially more costly, time- consuming, and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline. The FDA requires every manufacturer to make this modification determination in the first instance, but the FDA may review any manufacturer' s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510 (k) clearances were not required. We may make similar modifications or add additional enhancements or features in the future that we believe do not require a new 510 (k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510 (k) notifications, de novo classifications, or PMAs for modifications to our previously authorized products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any ~~48delay~~ -- **delay** or failure in obtaining required clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations. The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA' s Quality System Regulation (QSR) which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved devices in the United States. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing. Foreign regulatory authorities also impose manufacturing quality requirements, which may differ from the FDA requirements, with which we must comply. ~~We~~ **49We** or our third- party suppliers and manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or foreign jurisdiction requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA' s refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products;

and criminal prosecution of us or our employees. Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenues and increased costs. If treatment guidelines for the clinical conditions we are targeting change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products. If treatment guidelines for the clinical conditions we are targeting or the standard of care for such conditions evolves, we may need to redesign the applicable product and seek new clearances or approvals from the FDA. Our existing 510 (k) and de novo clearances from the FDA are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could suffer. The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies, particularly if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Our product has been authorized for marketing by the FDA for a specific indication. We train our commercial organization and distributors inside and outside the United States to not promote our products for uses outside of the FDA- cleared indications for use, known as " off- label uses. " However, we cannot guarantee that all of our employees, representatives, and agents will abide by our marketing policies. ~~49If~~ **If** the FDA or any foreign regulatory body determines that our promotional materials, training, or other marketing activities constitute promotion of an off- label or unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violations that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as laws prohibiting false claims for reimbursement. Moreover, even if we, and all our employees, contractors, and agents, market our products in compliance with applicable FDA regulations, such regulations do not apply to the practice of medicine, and we cannot prevent a physician from prescribing and / or using our products off- label when, in the physician' s independent professional medical judgment, he or she deems it appropriate. Similarly, we cannot prevent patients from using our products off- label. There may be increased risk of injury to patients if physicians attempt to prescribe, or patients attempt to use, our products off- label. Furthermore, the use of our products for indications other than those authorized by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. There are similar risks if our products are used off- label with respect to non- U. S. regulatory approvals. ~~Our~~ **50Our** products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report or Safety Alert to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation. ~~50Depending~~ -- **Depending** on the corrective action we take to redress a product' s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any adverse event involving our products could result in voluntary corrective actions, such as recalls or customer notifications, or agency action, such as

inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as exposing us to private litigation, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. ~~If~~ **51If** we or our distributors do not obtain and maintain international regulatory registrations or approvals for our products, we will be unable to market and sell our products outside of the United States. Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time- consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country. Regulatory clearance or approval by the FDA and / or the permission to affix the CE Mark does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others. We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, 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. There are numerous U. S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti- kickback, false claims and physician transparency laws. Our business practices and relationships with providers, patients and third- party payors are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government in ~~51addition~~ -- **addition** to the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include: ● the federal Anti- Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term " remuneration " has been broadly interpreted to include anything of value. The government can establish a violation of the Anti- Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. Moreover, the government may assert that a claim for reimbursement that includes items resulting from a violation of the federal healthcare Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (" FCA ") ~~, as described in more detail below~~ . Although there are a number of statutory exceptions and regulatory safe harbors to the federal healthcare Anti- Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly ~~and in order to obtain protection from a safe harbor the entities involved must meet every element~~ . ~~Accordingly, industry practices~~ **Practices** that involve ~~providing~~ remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or a safe harbor. **Our practices may** ~~It is possible that~~ not **in** all **cases** ~~our practices may not~~ meet all of the criteria for safe harbor protection from anti- kickback liability. Moreover, there are no safe ~~harbors~~ **52harbors** for many common practices, such as reimbursement support programs, educational or research grants, or charitable donations; ● the federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. The Social Security Act also has a provision that provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or Medicaid beneficiary that such person knows or should know is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service payable by a federal health care program ~~,~~ **. Private individuals commonly** known as **"** ~~beneficiary inducement. Whistleblowers~~ **whistleblowers , "** can bring FCA qui tam actions on behalf of the government and themselves, and may share in amounts paid by the entity to the government in recovery or settlement. ~~FCA~~ **False Claims Act** liability **is** ~~can be~~ potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $ ~~11~~ **13** , ~~803~~ **946** to $ ~~23~~ **27** , ~~607~~ **894 (beginning in 2024)** per false or fraudulent claim or statement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial settlements under the FCA in connection with alleged off label promotion of their ~~products, providing improper renumeration to healthcare providers or other personnel involved in recommending~~ products, and allegedly providing free products to customers with the expectation that the customers would bill federal health care programs for the product. In addition, 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 FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes " any request or demand " for money or property presented to the U. S. government.

~~Thus~~ **In addition** , ~~medical device~~ manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting false, fictitious or fraudulent claims to the federal government; ~~52~~ ● **the federal physician self- referral law** ~~The Health Insurance Portability and Accountability Act of 1996~~ (" ~~HIPAA~~ **Stark Law** ") **prohibits** , **subject to exceptions, referring Medicare patients for " designated health services " (including " durable medical equipment and supplies " and " outpatient hospital services ") (" DHS ") to entities with which a referring physician (or immediate family member) maintains a " financial relationship. " States (as required in order to maintain Medicaid funding) have further enacted similar prohibitions that apply to Medicaid, as well as other insurance programs, and which may be more restrictive than the Stark Law. Persons who attempt to circumvent these laws or submit (or cause others to submit) claims to payors in violation of these laws may be subject to significant civil and criminal penalties. As such, we are generally prohibited from billing for any services referred in violation of these laws. Importantly, we do not provide DHS and do not bill payors for DHS (or any other items or services). While we manufacture and sell equipment and supplies to our customers, we are not a Medicare supplier. Additionally, in instances in which we maintain contractual arrangements with physicians or hospitals, we have no reason to believe that we are engaged in assisting any person with circumventing these laws. Further, the services (specifically TMS) furnished (outside of a hospital context) by physician groups with whom we maintain contractual arrangements do not constitute DHS. Notably, however, the Stark Law is a strict liability statute and compliance is difficult to assure; ● HIPAA** among other ~~regulatory requirements described below~~ **things established various criminal health care fraud laws** , ~~also~~ **which** ~~imposes~~ **impose** criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, ~~fictitious~~ **53fictitious** or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the **applicable** statute or specific intent to violate it or to have committed a violation; ● HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security, transmission and breach reporting obligations with respect to individually identifiable health information upon " covered entities " subject to the law, including health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates that perform services on their behalf that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions ~~. On December 10, 2020, the U. S. Department of Health and Human Services Office for Civil Rights issued a Notice of Proposed Rulemaking, which if finalized, would make changes to some of HIPAA' s regulatory requirements, which would apply to business associates~~ ; ● the federal **physician payment transparency requirements, sometimes referred to as the "** Physician Payments Sunshine Act **"** created under the PPACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children' s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicare Services ~~, or~~ **(“** CMS **”)** , information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists ~~,~~ **and** chiropractors ~~,~~ **) other professionals (** physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and ● foreign and state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non- governmental third- party payors, including private insurers; state laws that require device manufacturers to comply with the industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and other federal and state laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health- related and other personal information, many of which differ from each other in significant ways and often are not pre- empted by HIPAA, thus requiring additional compliance efforts and data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the **GDPR** ~~General Data Protection Regulation~~ , which became effective in May 2018). These laws and regulations, among other impacts, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with ~~53psychiatrists~~ **psychiatrists** , other healthcare provides, or other potential purchasers of our products. We have also entered into consulting agreements with physicians, which are subject to these laws. Further, while we do not submit claims to any payor and our customers make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. ~~To~~ **54To** enforce compliance with healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of

interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations and oversight if we becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. Healthcare policy changes, including recently enacted legislation reforming the U. S. healthcare system, could harm our cash flows, financial condition and results of operations. From time to time, Congress drafts legislation that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations, revisions, or reinterpretations of existing regulations may impose additional costs, lengthen review times of any future products, or make it more difficult to manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. For example, in March 2010, the PPACA was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the PPACA: ● establishes a new Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; ● **required manufacturers to report certain payments and other transfers of value pursuant to the Physician Payments Sunshine Act, described above; ●** implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, psychiatrists and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and ● expands the eligibility criteria for Medicaid programs **and, originally, required certain employers to provide, and all individuals to obtain, health insurance** . We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. ~~54Our~~ -- **Our** employees, distributors, and other third parties may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, distributors, and other third parties may engage in inappropriate, fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or ~~negligent~~ **55negligent** conduct or other unauthorized activities that violate ~~the~~ **, regardless of intent,** regulations of the FDA and other U. S. healthcare regulators, as well as non- U. S. regulators, including by violating laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale **, promotion and labeling** of medical devices **or arrangements with healthcare providers** , are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing **, patient steering** and other abusive practices, as described herein. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer **or patient** incentive programs, and other business **, investment or compensation** arrangements. It is not always possible to identify and deter misconduct by our employees, distributors, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Efforts to ensure that the activities of these parties will comply with applicable healthcare laws and regulations involve substantial costs. These risks may **exceed those which** ~~be more pronounced, and~~ we ~~may find that~~ **have identified, and** the processes and policies we have implemented ~~are~~ **may** not ~~effective at~~ **be sufficient to** ~~preventing~~ -- **prevent** misconduct. **Noncompliance may** ~~If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could~~ result in the imposition of significant fines or other sanctions, including ~~the imposition of~~ civil, criminal and administrative penalties, **monetary** damages, ~~monetary~~ fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we becomes 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 the curtailment of our operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations. Risks Related to Our Capital StructureWe may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations. If our available cash balances, potential future borrowing capacity, and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products as a result of the risks described in this Annual Report on Form 10- K, we may seek to sell common or preferred equity or debt securities, enter into an additional credit facility or another form of third- party funding or seek other debt financing. Our present and future funding requirements will depend on many other factors, including: ● our ability to achieve revenue growth and improve operating margins; ● our ability to **comply with financial and other restrictive covenants in our credit facility, which, among other things, requires us to maintain specified financial covenants; ● our ability to** improve or maintain coverage

and reimbursement arrangements with domestic third- party and government payors; ● our rate of progress in establishing coverage and reimbursement arrangements from international commercial third- party and government payors, particularly in Japan; ● the cost of expanding our operations and offerings, including our sales and marketing efforts; ~~55~~ ● our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products and maintaining or improving our sales to our current customers; **56** ● the cost of research and development activities, including research and development relating to additional indications; ● the effect of competing technological and market developments; ● costs related to international expansion; and ● the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products. We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to: ● expand our sales and marketing efforts to increase market adoption of our products and address competitive developments; ● fund development and marketing efforts of any future products or additional features to then- current products; ● acquire, license or invest in new technologies; ● provide for supply and inventory costs associated with plans to accommodate potential increases in demand for our products ● acquire or invest in complementary businesses or assets; and ● finance capital expenditures and general and administrative expenses. Additional capital may not be available to us at such times or in the amounts we need. Even if capital is available, it might be available only on unfavorable terms. Any issuance of additional equity or equity- linked securities could be dilutive to our existing stockholders, and any new equity securities could have rights, preferences and privileges superior to those of holders of our common stock, including the shares of common stock sold in this offering. Debt financing, if available, may involve covenants **further** restricting our operations or our ability to incur additional debt, pay dividends, repurchase our stock, make investments and engage in merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish or license some rights to our technologies or products, on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired and we may be required to cease operations, curtail one or more product development or commercialization programs, significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all our assets. Our ability to use net operating losses..... effectively increasing our future tax obligations. The terms of our credit facility place restrictions on our operating and financial flexibility **and could subject us to potential default** . If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. ~~In March~~ **On September 29,** ~~2020~~ **2023** , ~~we~~ **the Company** entered into a ~~$ 50. 0 million credit facility~~ **fifth amendment (the " Solar Fifth Amendment ") to the Loan and Security Agreement dated March 2, 2020** with SLR Investment Corp. (formerly known as Solar Capital Ltd.) ~~, or~~ (" Solar "), **as collateral agent, and the lenders as defined in the agreement,** that is secured by a lien covering substantially all of our assets **(as amended, the " Solar Facility ")** . The credit facility contains customary covenants and events of default applicable to us. The affirmative covenants include, among others, a covenant that requires us to achieve agreed amounts of trailing twelve month net product revenue (" net product revenue covenant "), measured monthly through the term of the credit facility. The negative covenants include, among others, restrictions on us transferring collateral, changing businesses, engaging in ~~mergers~~ **57mergers** or acquisitions, incurring additional indebtedness and encumbering collateral. If we default under the credit facility, Solar may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, Solar' s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Solar could declare a default upon the occurrence of any event that it interprets as a material adverse effect as defined under the credit facility, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by Solar of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. In **certain months of** ~~2020~~ **2023** and 2021, we did not achieve the required revenue under the net product revenue covenant **and** ~~, but~~ we obtained waivers from Solar to cure the ~~breach~~ **non- compliance** of the net product revenue covenant. **We cannot provide any assurance that our lender would** ~~In 2022 we achieved the required revenue under the net product revenue covenant. If we fail to achieve the specified level of product net revenue in the future, Solar is under no obligation to~~ provide us with ~~relief~~ **a waiver should we not be in compliance in the future. A failure to maintain compliance along with our lender not agreeing to a waiver** for **the non- compliance would cause the outstanding borrowings to be in default and payable on demand which would have a material adverse effect on us and our ability to continue as a going concern. Our ability to comply with financial covenant tests can be affected by events beyond our control, including economic, financial and industry conditions. If market or other economic conditions deteriorate, our ability to comply with these covenants may be impaired. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our existing or** future ~~specified defaults not be able to refinance our existing or future debt,sell assets,borrow more money or raise equity on terms acceptable to us,if at all.~~ Our ability to use net operating losses to offset future taxable income may be subject to limitations.As of December 31, ~~2023~~ **2022** ,we had federal and state net operating loss carryforwards of $ ~~338~~ **312** . ~~0~~ **7** million and $ ~~217~~ **197** . ~~1~~ **2** million,respectively.The federal and state net operating loss carryforwards will begin to expire,if not utilized,beginning in ~~2024~~ **2023 ,respectively** .These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities.Under the newly enacted federal income tax law,federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely,but the deductibility of such federal net operating losses is limited.It is uncertain how various states will respond to the newly enacted federal tax law.In addition,under Section 382 of the Internal Revenue Code of 1986,as amended, ~~and~~ **56and** corresponding provisions of state law,if a corporation undergoes an " ownership change," which is generally defined as a greater than 50 % change,by value,in its equity ownership over a three- year period,the corporation' s ability to use its pre- change net operating loss carryforwards and

other pre- change tax attributes to offset its post- change income or taxes may be limited.We have not done an analysis to determine whether or not ownership changes have occurred since inception and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership,some of which may be outside of our control.If an ownership change occurs and **our ability to use our net operating loss carryforwards is materially limited,it would harm our future operating results by effectively increasing our future tax obligations.** . Risks Related to Ownership of Our Common StockThe price of our common stock has been and may continue to be volatile. The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Factors that could cause volatility in the market price of our common stock include, but are not limited to: ● the actual or anticipated fluctuations in our financial condition and operating results; **58** ● the actual or anticipated changes in our growth rate; ● the commercial success and market acceptance of our products; ● the success of our competitors in developing or commercializing products; ~~57~~ ● media exposure of our products or of those of others in our industry; ● our ability to commercialize or obtain regulatory approvals for our products, or delays in commercializing or obtaining regulatory approvals; ● announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; ● the addition or departure of key personnel; ● product liability claims; ● general prevailing economic, industry and market conditions, including factors unrelated to our operating performance or the operating performance of our competitors; ● business disruptions caused by earthquakes, fires, pandemic diseases (such as from coronavirus), or other natural disasters; ● disputes or other developments concerning our intellectual property or other proprietary rights, including litigation; ● the FDA or other U. S. or foreign regulatory actions affecting us or the healthcare or medical device industry; ● healthcare reform measures in the United States; ● third- party payor developments in the United States and other countries; ● sales of our common stock by our directors, officers, or stockholders; ● the timing and amount of our investments in the growth of our business; ● inability to obtain additional funding; ● future sales or issuances of equity or debt securities by us; ● failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; and ● the issuance of new or changed securities analysts' reports or recommendations regarding us. In addition, the stock markets in general, and the markets for companies like ours in particular, have from time to time experienced extreme volatility that has been often unrelated to the operating performance of the company. These broad market and industry fluctuations may negatively impact the price or liquidity of our common stock, regardless of our operating performance. ~~Moreover~~ **59Moreover** , because of these fluctuations, comparing our operating results on a period- to- period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline ~~58substantially~~ **substantially** . Such a stock price decline could occur even when we have met any previously publicly stated revenues or earnings forecasts that we may provide. Future sales of our common stock or securities convertible or exchangeable for our common stock may cause our stock price to decline. If our stockholders or option holders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the price of our common stock could decline. The perception in the market that these sales may occur could also cause the price of our common stock to decline. Shares of common stock that are either subject to outstanding options, or are outstanding but subject to vesting or reserved for future issuance under our 2018 Equity Incentive Plan **(** ~~, or~~ the **"** 2018 Plan **")** , will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act. We have also filed a registration statement permitting certain shares of common stock issued under our 2003 Stock Incentive Plan, or the 2003 Plan, and shares of common stock issued pursuant to the 2018 Plan or our 2018 Employee Stock Purchase Plan **(** ~~, or~~ the **"** 2018 ESPP **")** , to be freely resold by plan participants in the public market, subject to applicable vesting schedules and, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. Both the 2018 Plan and the 2018 ESPP contain provisions for the annual increase of the number of shares reserved for issuance under such plans, which shares we also intend to register. If the shares we may issue from time to time under the 2003 Plan, the 2018 Plan or the 2018 ESPP are sold, or if it is perceived that they will be sold, by the award recipients in the public market, the price of our common stock could decline. Certain shares of common stock are entitled to rights with respect to registration under the Securities Act. Such registration would result in these shares becoming fully tradable without restriction under the Securities Act when the applicable registration statement is declared effective. Sales of such shares could cause the price of our common stock to decline. Our principal stockholders and management own a significant percentage of our stock and are able to exert control over matters subject to stockholder approval. As of February ~~27~~ **29** , ~~2023~~ **2024** , our officers and directors, together with holders of 5 % or more of our outstanding common stock and their respective affiliates, beneficially owned approximately **10** ~~20. 7~~ % of our outstanding common stock. Accordingly, these stockholders have a material influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, mergers, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise. ~~Provisions~~ **60Provisions** of our amended and restated charter documents or Delaware law could delay or prevent an acquisition of the company, even if the acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a

merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or ~~59remove~~ -- **remove** our current management by making it more difficult to replace or remove our board of directors. These provisions include: ● a prohibition on stockholder action through written consent; ● no cumulative voting in the election of directors; ● the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director; ● a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president; ● an advance notice requirement for stockholder proposals and nominations; ● the authority of our board of directors to issue blank- check preferred stock with such terms as our board of directors may determine; and ● a requirement of approval of not less than 66 2 / 3 % of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our amended and restated certificate of incorporation. In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15 % or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company. Provisions in our charter documents and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, other than an action or suit to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the ~~DGCL~~ **Delaware General 61Corporation Law** or our amended and restated certificate of incorporation or amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. ~~60Some~~ -- **Some** companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. We have never declared or paid any cash dividends on our common stock and do not intend to do so in the foreseeable future. We currently intend to retain all available funds and any future earnings to finance the growth and development of our business. In addition, the terms of our credit agreements contain, and the terms of any future credit agreements we may enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. If securities or industry analysts do not publish research or reports about our business, or publish inaccurate or unfavorable research or reports about our business, our stock price and trading volume could decline. The trading market for our common stock depends, to some extent, on the research and reports that securities or industry analysts publish about us and our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline. If one or more of these analysts cease to cover us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline. General Risk FactorsWe may be subject to securities litigation, which is expensive and could divert our management' s attention. In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management' s attention from other business concerns. ~~We are an " emerging growth~~ **While we currently qualify as a smaller reporting** company ~~" and~~ **under SEC regulations, we cannot be certain whether taking advantage of** the reduced disclosure requirements applicable to **these** ~~emerging growth~~ companies ~~could~~ **will not** make our common stock less attractive to investors. ~~We~~ **Once we lose smaller reporting company status, the costs and demands placed upon our management** are **expected to** ~~an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. We may remain an emerging growth company until as late as December 31, 2023, though we may cease~~ **increase** ~~to be an emerging growth company earlier under certain circumstances, including (i) if the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of any June 30, in which case we would cease to be an emerging growth company as of the following December 31, or (ii) if our gross revenues exceeds $ 1~~ . **The SEC' s rules permit smaller reporting** ~~07 billion in any fiscal year. " Emerging growth~~ companies **to** ~~" may~~ take advantage of

certain exemptions from various reporting requirements ~~that are~~ applicable to other public companies **. As long as we qualify as a smaller reporting 62company** , ~~including not being~~ **based on our public float, and report less than $ 100 million in annual revenues in a fiscal year we are permitted, and we intend to, omit the auditor' s attestation on internal control over financial reporting that would otherwise be** required **by** ~~to comply with the auditor attestation requirements of Section 404 of~~ the Sarbanes- Oxley Act **. Our status as an emerging growth company expired as of December 31** , ~~reduced~~ **2023. While we expect to remain a smaller reporting company and non- accelerated filer, we now face increased** disclosure ~~obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the~~ requirements **as** ~~of holding~~ a ~~nonbinding~~ **non- emerging growth company, such as stockholder** advisory ~~vote~~ **votes** on executive compensation **(" say- on- pay ")** ~~and stockholder approval of any golden parachute payments not previously approved~~ . **Until such time that we lose smaller reporting company status, it is unclear if** ~~Investors~~ **investors** ~~could~~ **will** find our common stock less attractive because we may rely on ~~these~~ **certain disclosure** exemptions. If ~~61some~~ -- **some** investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile ~~. In addition, Section 102 of the JOBS Act also provides that an~~ **and could cause our stock price to decline. As a result of the loss of our** emerging growth company ~~can take advantage of~~ **status, we expect** the **costs and demands placed upon our management to increase** ~~extended transition period provided in Section 7 (a) (2) (B) of the Securities Act of 1933~~ , as ~~amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing not to " opt out " of such extended transition period, and as a result,~~ we ~~will not~~ **now have to** comply with ~~new or revised~~ **additional disclosure and** accounting ~~standards~~ **requirements. In addition, even if we remain a smaller reporting company, if our public float exceeds $ 75 million and we report $ 100 million or more in annual revenues in a fiscal year, we will become subject to the provisions of Section 404 (b) of the Sarbanes- Oxley Act requiring an independent registered public accounting firm to provide an attestation report** on the **effectiveness** ~~relevant dates on which adoption~~ of ~~such standards is required for non- emerging growth companies~~ **our internal control over financial reporting, making the public reporting process more costly** . We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and the value of our common stock. As a public company, **we are required under** the Sarbanes- Oxley Act **to** ~~requires that we~~ maintain effective disclosure controls and procedures and internal control over financial reporting. We have developed disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and regulations, and that information required to be disclosed in reports under the Exchange Act, is communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations reflect the reality that judgments can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Any failure to maintain effective controls could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will be required to include in periodic reports we file with the SEC under Section 404 of the Sarbanes- Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes- Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on the Nasdaq Global Market. Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting due to our status as a smaller reporting company (" SRC "). **63** ~~Pursuant to the Exchange Act Continuous Disclosure Accommodations, the auditor attestation requirement of section 404 (b) of the Sarbanes Oxley Act of 2002 is not required by SRCs, with public common equity float between $ 75 million and $ 700 million and annual revenues of less than $ 100 million. 62~~