Risk Factors Comparison 2024-03-12 to 2023-03-01 Form: 10-K

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

Risks Related to Our Business and Industry Our business, financial condition, and results of operations may be adversely affected by **general economic** ~~the continuing effects of COVID- 19,~~ and ~~the~~ **financial market conditions and** current and future social and geopolitical instability ~~and~~ **. Changes in** domestic and **global economic conditions, supply chain disruptions, labor shortages, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to increased costs and may cause changes in fiscal and monetary policy. The world' s financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation,** foreign ~~economic~~ **currency fluctuations** and ~~financial~~ **volatility in the valuations of securities generally. As a result, our** ~~instability~~ ---- **ability** **. In March 2020,** ~~,~~ **to access capital markets and** ~~the~~ **other funding sources** ~~World Health Organization characterized the spread of a novel strain of coronavirus (" COVID- 19 ") as a global pandemic, and the President of the U. S. later proclaimed that the COVID- 19 outbreak~~ in the **future may not be available on commercially reasonable terms** ~~U. S. constituted a national emergency. Extraordinary actions were taken by federal~~ , **if** ~~state and local governmental authorities to combat the spread of COVID- 19, including issuances of " stay-~~ at ~~- home " directives~~ **all. Impacts from inflationary pressures, such** ~~and~~ - **an increasing costs** ~~similar mandates that substantially restricted daily activities and~~ for ~~many~~ **research and development of our products, administrative and other costs of doing** ~~businesses~~ -- **business** ~~curtailed or ceased normal operations. These measures led to reduced economic activity~~ , **could** ~~including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80 % of the number of surgical procedures using the Company' s ClearPoint system. Although economic activity is returning to normalized levels, the effects of COVID- 19 and the progression of the virus in certain geographies may still have an effect on curtailing the performance of elective procedures, and may thus~~ adversely affect our ~~business,could adversely affect our~~ business,financial condition and results of operations.Additionally,our customers could experience financial and operational pressures as a result of **macroeconomic conditions,such as** labor shortages, ~~the~~ supply chain disruptions,and increased inflation, **any of** which could impact their ability to access capital markets and other funding sources,increase cost of funding,cause cash flow problems,or impede their ability to comply with debt covenants,which in turn could impede their ability to provide patient care,conduct further research and development,marketing and commercialization efforts,or impact their profitability.To the extent that our customers continue to face such financial pressures,it could impact their willingness to spend on our ~~product~~ **products** ~~revenues~~ **and services or their ability to make payment, either of which could adversely affect our business, financial condition and results of operations** . The global economy has been, and may continue to be, negatively impacted by the ongoing conflict resulting from Russia' s invasion of Ukraine in 2022, **uncertainty in the Middle East region,** or the increasing tensions between China and Taiwan. The negative impacts arising from the conflict and sanctions and export restrictions imposed by various countries, including those imposed by Russia, may include reduced consumer demand, supply chain disruptions, increased cybersecurity risks, and increased costs for transportation, energy, and raw materials. Although the majority of our operations do not take place in Russia, Ukraine **, Israel** , China, or Taiwan, further escalation of geopolitical tensions could have a broader impact that expands into other markets where we do business, which may adversely affect our business, financial condition..... our products and services, which could adversely affect our business, financial condition and results of operations. Although, to date, our business has not been materially impacted by the ongoing geopolitical tensions, inflation, supply chain disruptions or labor shortages, it is impossible to predict the extent to which our operations could be impacted in the short or long term, or the ways in which such matters may impact our business. If we cannot maintain our current relationships, or enter into new relationships, with drug delivery customers, our revenue prospects could be reduced. We collaborate with pharma / biotech, academic, and contract research organization customers (collectively " drug delivery customers ") to provide products and services in connection with ~~pre- clinical~~ **preclinical** and clinical studies. The revenue attributable to our drug delivery customers may fluctuate in the future, which could have a material adverse effect on our financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue. Our future success depends in part on our ability to maintain these relationships and to establish new relationships. Many factors have the potential to impact such collaborations, including the ability to deliver therapies to our drug delivery customers' satisfaction, regulatory approval, perceptions in connection with the safety of therapies or delivery mechanisms, our customers' ability to access adequate and sustainable financing, and other factors that may be beyond our control. Furthermore, our drug delivery customers may decide to decrease or discontinue their use of our products and services due to changes in research and product development plans, failures in their clinical trials, financial constraints, utilization of internal resources or services performed by other parties. In addition to reducing our revenue, the loss of one or more of these relationships may reduce our exposure to research and clinical trials that further our business objectives. We engage in conversations with drug delivery customers regarding potential opportunities on an ongoing basis. There is no assurance that any of these conversations will result in an agreement, or if an agreement is reached, that the resulting relationship will be successful or that **preclinical,** clinical **,** or research studies conducted as part of the engagement **will be continued or** will produce successful outcomes. The sizes of the markets for our products and services and any future products and services may be smaller than we estimate and may decline. Our estimates of the total addressable market for our products and services are based on a number of internal and third- party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our products and services in the market. While we believe our assumptions and the data underlying our estimates are reasonable, these

assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our products and services in different market segments may prove to be incorrect. If the actual number of patients with indications who would benefit from our products, the price at which we can sell our products or the annual total addressable market for our products is smaller than we have estimated, it may impair our prospective market and revenue opportunity. Our ClearPoint system may not achieve broad market adoption. To date, a substantial majority of the sales of our ClearPoint System have been derived from a limited number of hospitals. Our future growth depends on our ability to increase physician and patient awareness of our products, and on the willingness of hospitals to adopt our products for their neurosurgical procedures. Our ClearPoint system may not gain broad market adoption unless we continue to convince physicians, hospitals and patients of its benefits. Moreover, even if physicians and hospitals understand the benefits of our ClearPoint system, they still may elect not to use our ClearPoint system for a variety of reasons, such as: • the shift in location of the procedure from the operating room to the MRI suite; • demand for the MRI suite within the hospital, which may result in limited or no MRI scanner availability for procedures in which our ClearPoint system would be used; • the familiarity of the established physician with other devices and surgical approaches; • lack of exposure to the ClearPoint system in the fellowship training period where preferences for surgical methods are formed; • the physician' s perception that there are insufficient benefits of our ClearPoint system relative to those other devices and surgical approaches; • budgetary constraints with respect to the purchase of our ClearPoint system hardware and software; • hospital infection control procedures; • the price of our ClearPoint system disposable products, which may be higher than devices used with other surgical approaches; and • the physician' s perception that there is a lack of clinical data on the use of our ClearPoint system. Our ability to execute our growth strategy and become profitable depends upon the adoption by physicians and hospitals of the ClearPoint system for use in neurosurgical procedures. Historically, a substantial portion of our revenue is generated from sales of the disposable products utilized with our ClearPoint system, and we are therefore highly dependent on growing the installed base of the ClearPoint system for our success. We cannot provide assurance that our ClearPoint system will achieve broad market acceptance among hospitals, physicians, or patients. Any failure of the ClearPoint system to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations. A portion of our future business growth is dependent upon marketing and selling our ClearPoint system, and other new products, in the operating room, and if we are unable to expand, manage and maintain our marketing and sales capabilities in this environment, we may be unable to generate significant growth in our product revenues. We started selling our ClearPoint system in August 2010, and to date, sales of the ClearPoint system have been **primarily** focused on its use for neurosurgical procedures in the MRI suite. In 2021, we launched the SmartFrame Array Neuro Navigation System and Software, ~~which~~ **and in 2024, we commenced limited market release of the SmartFrame OR Stereotactic System. Both SmartFrame Array and SmartFrame OR** ~~allows~~ **allow** for operating room placement of our technology. We have relatively limited experience marketing and selling our ClearPoint system **and products** for use with neurosurgical procedures in the operating room. If our team fails to adequately promote, market and sell the ClearPoint system, and other new products that we may develop in the future, in this new environment, our sales could suffer. Additionally, our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. To achieve our business objectives, we must continue to grow. However, continued growth presents numerous challenges, including: • expanding our sales, clinical support, product development and marketing infrastructure and capabilities; • expanding our assembly capacity and increasing production; • implementing appropriate operational and financial systems and controls; • improving our information systems; • identifying, attracting and retaining qualified personnel in our areas of activity; and • hiring, training, managing and supervising our personnel. We cannot be certain that our systems, controls, infrastructure and personnel will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products and our business will be harmed. Our long- term growth depends on our ability to compete effectively in the neurosurgery market by developing and commercializing new products and services through our research and development efforts, independently and through third-party collaborations. Our future business prospects depend in part on our ability to develop and commercialize new products and services, such as the Maestro Brain Model, the ClearPoint Prism Neuro Laser Therapy System, ~~Pre- Clinical~~ **SmartFrame OR, and preclinical** ~~Development~~ **development and device development** ~~Services~~ **services** for ~~Pharmaceutical~~ **pharmaceutical** ~~Partners~~ **partners** ~~, and the Robotic- Assisted Navigation system~~ . New technologies, techniques or products could emerge from competitors that might offer better combinations of price and performance than our products and services. It is important that we anticipate changes in technology and market demand, as well as customer preferences and practices, to successfully commercialize new technologies to meet our prospective customers' needs on a timely and cost- effective basis. We might be unable to successfully commercialize our marketed products or services or obtain authorization to market new products. The success of any new product offering will depend on numerous factors, including our ability to: • properly identify and anticipate customer needs; • identify, retain, and manage third- party design and development firms, where appropriate, to accelerate development; • develop and introduce new products or services in a timely manner; • adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; • obtain and retain third- party licenses required for the development, commercialization, and / or utilization of new products; • demonstrate the safety and efficacy of new products; • obtain the necessary regulatory authorizations to market new products or product enhancements; • deliver products and services at a price point that is both profitable and acceptable to the market; and • secure our supply chain to ensure we can continue to deliver products in a timely fashion to all geographies. If we do not develop and obtain regulatory authorization to market new products in time to meet market demand, or if there is insufficient demand for these products, our results of operations will suffer. Our internal research and development efforts and our outsourced third- party design and development initiatives 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. In the ordinary course of our development and commercialization of new products and services, we may enter into collaborations, in- licensing arrangements, joint development, distribution, or other commercial arrangements. Proposing, negotiating and implementing such arrangements may be a lengthy, expensive, and complex process. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost- effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these arrangements may not result in the development of products or services that achieve commercial success or result in significant revenues and could be terminated prior to achieving their desired objectives. A growing part of our revenue from the biologics and drug delivery business is derived from providing consultancy to our pharmaceutical and other medical technology partners for ~~pre- clinical~~ **preclinical** development services, on- site clinical support and training, regulatory consultation, protocol consultation, customized device development, and other solutions to optimize ~~pre- clinical~~ **preclinical** and clinical workflows. In certain cases, these services support a novel area in which commercialization must be preceded by **preclinical studies and** FDA- mandated clinical trials, which are expensive and time consuming to conduct, and for which the commercial success is uncertain, pending, in part, the outcome of those **studies and** trials. The ~~continuation~~ **maintenance** and growth of our revenue from our biologics and drug delivery services is dependent on our pharmaceutical and other medical technology partners **continuing their development process and** achieving commercial success with their therapeutic products **. Some of our customers and partners may elect to terminate or renegotiate their agreements with us for various reasons, including force majeure clauses, unexpected or undesired study results, dissatisfaction with our performance under the agreement, the loss or limitation of funding for research and development, or general convenience. Cancellation or renegotiation of a large agreement could adversely affect our business and, therefore, may adversely affect our operating results. In addition, we may enter into agreements with customers to provide services on a fixed fee basis. We may also enter into agreements with customers for which we are paid a lump sum conditioned upon the achievement of our customer' s development milestones. Accordingly, in these cases, we bear the risk if we underprice our contracts, overrun our cost estimates, or if there is a failure by our customer to achieve the development milestones. Such events could have an adverse effect on our business, results of operations, financial condition and cash flows** . If coverage and reimbursement from third- party payors for procedures utilizing our products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer. Our products are purchased ~~primarily~~ by hospitals, which bill various third- party payors, including governmental healthcare programs, such as Medicare, and private insurance plans, for procedures in which our products are used. Reimbursement is a significant factor considered by hospitals in determining whether to acquire and utilize medical devices. Therefore, our ability to successfully commercialize our products depends significantly on the adequacy of coverage and reimbursement from these third- party payors. Third- party payors, whether foreign or domestic, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the U. S., no uniform policy of coverage and reimbursement for medical device products and services exists among third- party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country- by- country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government- managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government- managed systems. Because in most cases, hospitals are reimbursed for the procedures in which our products are used and our products are not separately reimbursed, the additional cost associated with the use of our products could impact hospital profit margins. Some hospitals could believe third- party reimbursement levels are not adequate to cover the cost of our products. Furthermore, some physicians could believe third- party reimbursement levels are not adequate to compensate them for performing the procedures in which our products are used. Failure by hospitals and physicians, whether in the U. S. or abroad, to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and will limit our revenues and prospects for profitability. We currently have significant customer concentration, so economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business and operating results. A small number of our customers account for a substantial portion of our revenues. In ~~2022~~ **2023** , one pharmaceutical customer, a related party as described in Note 2 to the consolidated financial statements included elsewhere in this Annual Report, for whom we provide clinical services in support of the customer' s clinical trials and earn a quarterly fee, accounted for ~~15~~ **12** % of our total revenues, and ~~34~~ **21** % of our biologics and drug delivery revenue. Our five largest hospital customers account for approximately ~~26~~ **27** % of our functional neurosurgery navigation revenues. Revenues from almost all our customers are not based on long- term, committed volume purchase contracts, and we may not continue to generate a similar level of revenues from our largest customers, or any other customer. Because of our current customer concentration, our revenues could fluctuate, possibly significantly, due to a reduction or delay in our biotechnology and pharmaceutical customers' **preclinical studies or** clinical trials, or in orders from any of our

significant hospital customers, which could harm our business and results of operations. Our internal manufacturing operations are generally conducted at a single location, which may limit our ability to provide an adequate supply of our products, and any disruption at our manufacturing facility could render us unable to produce our products, increase our expenses and decrease our revenue. **Currently** ~~To date~~, final assembly of many of our products' components occurs at our ~~Irvine~~ **Carlsbad**, California facility, in an area that is at risk of experiencing serious fires and power outages and is considered to lie in an earthquake risk zone. If our facility experiences a disruption, we would have no other means of assembling those components until we are able to restore the manufacturing capability at our current facility or develop the same capability at an alternative facility. We do not maintain a backup manufacturing facility, making us dependent on our current facility for the continued operation of our business. A natural or other disaster could damage or destroy our manufacturing equipment and cause substantial delays in our manufacturing operations, which could lead to additional expense and decreased revenue due to lack of supply. The insurance we maintain may not cover, in whole or in part, our losses in any particular case. With or without insurance, damage to our facility or our other property due to a natural disaster or casualty event could have a material adverse effect on our business, financial condition and results of operations ~~. We may experience delays and disruptions in establishing an additional manufacturing facility in Carlsbad, California, and, once operational, we may not be successful operating such facility, which could adversely impact operating plans. Any such delays, disruptions or failure to successfully operate our manufacturing facility could result in interruptions in the development, manufacturing, and shipment of our products. In connection with the continued commercialization of our products, we have signed a lease for a manufacturing facility in Carlsbad, California, to " scale up " the production process of our components over the current level of production. The process of establishing manufacturing operations in a new facility is inherently complex. The establishment of the new facility and our expansion of our manufacturing operations may cause significant disruption to our operations, divert management' s attention and resources and will require significant capital expenditure, all of which could have a material adverse effect on our business, financial condition and operating results. If we encounter significant delays, cost overruns, engineering problems, equipment supply constraints, difficulty obtaining licenses and permits, or other serious challenges in making our new facility operational, we may be unable to meet our production goals in the time frame we have planned. We may not be successful in producing the amount and quality of products that we anticipate at our new facility and our operating results may suffer as a result. If we are unsuccessful in establishing our new manufacturing operations, we may become more reliant on and continue operations in our single manufacturing facility in Irvine, California. We may encounter challenges with extending our current facility lease and successfully expanding our operations over our current level of production. While we have taken steps in anticipation of growth, manufacturers often encounter difficulties in scaling up production, such as problems involving yields, quality control and assurance, and shortages of qualified personnel. If the scaled- up production process is not efficient or produces a product that does not meet quality and other standards, we may be unable to meet market demand and our revenues, business and financial prospects would be adversely affected. We can give no assurance that the development of our new facility will be completed as planned or within the anticipated timeframe, or that we will fully realize the expected benefits of such a facility~~. Our reliance on single- source suppliers for components ~~and~~ **,** finished products **and services** could harm our ability to meet demand for our products **or services** in a timely manner or within budget. Many of our components, component assemblies, and finished products are provided to us by single- source suppliers. We generally purchase components and component assemblies through purchase orders rather than long- term supply agreements. We generally do not maintain large volumes of inventory for components, component assemblies, or finished products. We have not identified alternative suppliers for some of the finished products that we commercialize. While alternative suppliers exist and have been identified for substantially all components, the disruption or termination of the supply of components and component assemblies could cause a significant increase in the cost of these components, which could affect our operating results. **We also depend on single- source service providers for many of the services that we perform for our customers.** Our dependence on a limited number of third- party suppliers and **service providers and** the challenges we may face in obtaining adequate supplies **and services** involve several risks, including limited control over pricing, availability, quality and delivery schedules. A disruption or termination in the supply of components or finished products could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Disruptions in the global supply chain could negatively affect our single- source suppliers and could further exacerbate the risk that we are unable to meet the demand for our products. Furthermore, if we are required to change the supplier of a key component or component assembly of our products, we may be required to verify that the new supplier maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. **Disruptions to our service providers could impact our ability to provide critical services to our customers, damage our customer relationships, and cause material adverse impacts to our financial results.** The delays associated with the verification of a new supplier **or service provider** could also adversely affect our ability to meet demand for our products **and services**. To the extent we seek a new indication for use of, or new claims for, our products, the FDA may not grant 510 (k) clearance or ~~premarket approval application (" PMA ")~~ approval of such new use or claims, which may affect our ability to grow our business. We received 510 (k) clearance to market our ClearPoint system for use in general neurosurgery interventional procedures, including DBS. We could seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurosurgical intervention claim. To the extent we seek expanded claims for our ClearPoint system, such claims could, depending on their nature, require 510 (k) clearance or FDA approval of a PMA. Moreover, some specific ClearPoint system claims could require clinical trials to support regulatory clearance or approval. In the event we seek a new indication for use of, or new claims for, the ClearPoint system that we believe are necessary or desirable for successful commercialization, the FDA may refuse our requests for 510 (k) clearance or PMA approval. Likewise, to the extent clinical trials are necessary, we may not successfully complete or have the funds to initiate such clinical trials. Our SmartFlow Cannula has received 510 (k) clearance from the FDA for use in the U. S. for the aspiration

of cerebrospinal fluid (“ CSF ”), or injection of Cytarabine into the ventricles. It has also been CE marked for use in ~~Europe~~ **the EU** for the delivery of approved fluids into the brain or aspiration of CSF. The SmartFlow Cannula is being utilized in approved combination product clinical and preclinical studies by pharmaceutical companies and academic research customers for various research and clinical trials in connection with delivery of therapeutic agents. The growth of our drug delivery and biologics business is dependent upon our pharmaceutical company customers’ ability to obtain regulatory approval for the use of the SmartFlow Cannula for delivery of their therapeutic agent, and / or our ability to expand the cleared indications for our SmartFlow Cannula to include delivery of our pharmaceutical company customers’ therapeutic agents. To the extent that our pharmaceutical partners are not successful in obtaining regulatory approval, or if we are unable to expand the cleared indications for use of our SmartFlow Cannula, we may not be able to grow our business. Clinical trials necessary to support 510 (k) clearance or PMA approval for any new indications for use of our products would be expensive and could require the enrollment of large numbers of suitable patients, who could be difficult to identify and recruit. Delays or failures in any necessary clinical trials would prevent us from commercializing any modified product or new product candidate and could adversely affect our business, operating results and prospects. Initiating and completing clinical trials necessary to support 510 (k) clearance or PMA approval for our existing products or any other product candidates that we may develop, or additional safety and efficacy data that the FDA may require for 510 (k) clearance or PMA approval for any new specific indications of our products that we may seek, would be time consuming and expensive with an uncertain outcome. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials. Conducting successful clinical trials could require the enrollment of large numbers of patients, and suitable patients could be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity to clinical sites of patients that are able to comply with the eligibility and exclusion criteria for participation in the clinical trial, and patient compliance. For example, patients could be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post- treatment procedures or follow- up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to our product candidates. Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy will be required and we may not adequately develop such protocols to support clearance or approval. Further, the FDA could require us to submit data on a greater number of patients than we originally anticipated and / or for a longer follow- up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial could cause an increase in costs and delays in the approval and attempted commercialization of our product candidates or result in the failure of the clinical trial. Such increased costs and delays or failures could adversely affect our business, operating results and prospects. If we fail to obtain the necessary clearances, certifications or approvals for our new products, our ability to grow our business globally could be harmed. Our business growth is dependent upon our ability to market and sell new products, including new therapy devices and devices to allow us to expand our business into the operating room. Unless and until we obtain FDA clearance, authorization or approval for the new products in our pipeline, we will not be able to sell or promote them in the U. S. Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510 (k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510 (k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, premarket submissions must be supported by clinical data. Clinical trials are expensive, time consuming, and their outcomes are uncertain. ~~Our ability to enroll patients in clinical trials could be impacted by the COVID- 19 outbreak, as many patients are electing or being asked to delay procedures at this time.~~ The PMA process typically is more costly, lengthy and stringent than the 510 (k) process and usually requires more substantial clinical studies. The FDA may not authorize marketing via de novo classification or clear our 510 (k) applications on a timely basis or at all. For example, during the peak of the COVID- 19 outbreak, the FDA experienced delays in the review of applications and concentrated their focus on products which addressed the COVID- 19 outbreak. Such delays or refusals, regardless of the cause, could have a material adverse effect on our business, financial condition, and results of operations. The FDA may also change its clearance and authorization policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay authorization or clearance of our products. Similar restrictions exist outside of the U. S. To sell our products in member countries of the EU, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93 / 42 / EEC). 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 EU. 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 (risk) classification. Except for low- risk medical devices (Class I non- sterile, non- measuring devices), where the manufacturer can self- declare 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 or licensed by a member state of the EU 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 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 and national member states laws, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EU. There is no assurance that future clearance or approval of our new products will be granted, or that we will be able to continue selling our products in any geography. Such failures could hurt our ability to maintain and grow our business. The results of our clinical trials may not support our product candidate claims or any additional claims we may seek for our products and may result in the discovery of adverse side effects. Even if any clinical trial that we need to undertake is completed as planned, we cannot be certain that its results will support our product candidate claims or any new indications that we may seek for our products or that the FDA or foreign authorities will agree with our conclusions regarding the results of those trials. The clinical trial process may fail to demonstrate that our products or a product candidate is safe and effective for the proposed indicated use, which could cause us to stop seeking additional clearances or approvals for our products or abandon or delay development of other product candidates. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize a product candidate. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate' s profile. The markets for medical devices are highly competitive, and we may not be able to compete effectively against the larger, well- established companies in our markets or emerging and small innovative companies that may seek to obtain or increase their share of the market. We will **continue to** face competition from products and techniques already in existence in the marketplace. The markets for medical devices used in neurosurgical procedures is intensely competitive, and many of our competitors are much larger and have substantially more financial and human resources than we do. Many have long histories and strong reputations within the industry, and a relatively small number of companies dominate these markets. Examples of such large, well- known companies include Medtronic, Abbott, Elekta and Brainlab. These companies enjoy significant competitive advantages over us, including: • broad product offerings, which address the needs of physicians and hospitals in a wide range of procedures and allow for price bundling; • greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks; • existing relationships with physicians and hospitals; • more extensive intellectual property portfolios and resources for patent protection; • greater financial and other resources for product research and development; • greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements; • established manufacturing operations and contract manufacturing relationships; and • significantly greater name recognition and more recognizable trademarks. We may not succeed in overcoming the competitive advantages of these large and established companies. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may introduce products that compete effectively against our products in terms of performance, price or both. We sell our products outside of the U. S., and we are subject to various economic, political, regulatory, and other risks relating to international operations, which could harm our revenue and profitability. We sell our products in several countries outside of the U. S. Our business strategy includes plans for expansion in countries where we currently operate as well as **the** ~~introducing~~ **introduction of** our products to other international markets. Doing business outside of the U. S. exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the U. S. are subject to different regulatory requirements in each jurisdiction where we operate or have sales. Our failure, or the failure of our distributors, to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or our distributors have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations. Engaging in business outside of the U. S. inherently involves a number of other difficulties and risks, including, but not limited to: • export restrictions and controls relating to technology; • pricing pressure that we may experience internationally; • difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • political and economic instability; • consequences arising from natural disasters and other similar catastrophes, such as hurricanes, tornados, earthquakes, floods and tsunamis; • potentially adverse tax consequences, tariffs and other trade barriers; • the need to hire additional personnel to promote our products outside of the U. S.; • international terrorism and anti- American sentiment; • fluctuations in exchange rates for future sales denominated in foreign currency ~~, which represent a majority of our sales outside of the U. S.~~; • difficulty in obtaining and enforcing intellectual property rights; and • changing regulatory environments such as the European Medical Device Regulation. In addition, our business practices in foreign countries must comply with U. S. laws, including the Foreign Corrupt Practices Act (" FCPA "). We have a compliance program in place designed to reduce the likelihood of potential violations of the FCPA and other U. S. and foreign anti- bribery and anti- corruption laws. If violations were to occur, they could subject us to fines and other penalties as well as increased compliance costs. Our exposure to each of these risks may increase our costs and require significant management attention. ~~We cannot assure you that one or more of these factors will not harm our business.~~ Disruptions of critical information systems or material breaches in the security of our systems could harm our business, customer relations and financial condition. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees ~~in our data centers,~~ on our networks, and on third party- controlled applications. The secure processing, maintenance and transmission of this information

is critical to our operations and business strategy. The information technology and infrastructure which we rely upon may be vulnerable to attacks by hackers or breached due to human error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, ~~disrupt~~ **disruption of** our operations and the services we provide to customers, and damage **to** our reputation and ~~cause a~~ loss of confidence in our products and services, which could adversely affect our business, operating margins, revenues and competitive position. In addition, the regulatory environment regarding data security and privacy evolves frequently and has become increasingly restrictive. We also rely in part on third- party information technology systems to store information, interface with customers, maintain financial accuracy, secure our data and accurately produce our financial statements. If our information technology systems do not effectively and securely collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, human error or cyber incident, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations would be materially impaired. Any such impairment could have a material adverse effect on our results of operations, financial condition and the timeliness ~~with~~ **in** which we report our operating results. Our insurance coverage related to information risks, breaches, and business interruption is subject to deductibles and coverage limitations. We may not be able to maintain our current insurance coverage on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against future claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against such information risks and breach claims, we could be exposed to significant liabilities. We may acquire other businesses, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense. As part of our business strategy, we may pursue acquisitions or investments in other companies or technologies. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. We have no experience with acquiring or investing in other companies and limited experience ~~with~~ **in** forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition or investment candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write- offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost- effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture. To finance any investments, acquisitions or joint ventures, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. We need to hire and retain additional qualified personnel to grow and manage our business. If we are unable to attract and retain qualified personnel, including our senior management team, our sales, clinical support and marketing team and our engineering team, our business and growth could be seriously harmed. Our performance depends on the talents and efforts of our employees. Our future success will depend on our ability to attract, retain and motivate highly skilled personnel in all areas of our organization, but particularly as part of our sales, clinical support, product development and marketing teams. We plan to continue to grow our business and will need to hire additional personnel to support this growth. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or fill new positions requiring key persons with appropriate experience, particularly in light of current labor market conditions. If we experience difficulties locating and hiring suitable personnel in the future, our growth may be hindered. Qualified individuals are in high demand, particularly in the medical device industry, and we may incur significant costs to attract and retain them. If we are unable to attract and retain the personnel we need to succeed, our business and growth could be harmed. All our employees, including the members of our senior management team, are at- will employees, and therefore they may terminate employment with us at any time. Accordingly, there are no assurances that the services of any of our employees will be available to us for any specified period of time. The loss of members of our senior management team, our sales, clinical support and marketing team or our engineering team, or our inability to attract or retain other qualified personnel, could have a material adverse effect on our business, financial condition, and results of operations. If the need to replace any of our key employees arises, the ~~replacement~~ **search and recruiting** process likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives. Risks Related to Our Financial Position We have incurred losses since our inception, and we may continue to incur losses. If we fail to generate significant revenue from sales of our products and services, we may never achieve or sustain profitability. We have incurred losses in each year since our inception in 1998 that have resulted principally from costs incurred in connection with our sales and marketing activities, research and development efforts, manufacturing activities and other general and administrative expenses associated with our operations, and we may continue to incur losses as we continue to invest capital in the sales and marketing of our ClearPoint platform products and services, and growth of our business generally. As a result of the numerous risks and uncertainties associated with developing medical devices and with our biologic and drug delivery customers' development of safe and effective drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our profitability will depend on revenues from the sale of our products and services. Additionally, increases in our various costs that may be the result of inflationary pressures could further reduce our sales and profitability. We cannot provide any assurance that we will ever achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our relatively limited

commercialization history **in our biologics and drug delivery business** , we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition. Any failure to achieve and maintain profitability would continue to have an adverse effect on our stockholders' equity and working capital and could result in a decline in our stock price or cause us to cease operations. We expect to need additional funding for our business, and we may not be able to raise capital when needed or on terms that are acceptable to us, which could force us to delay, reduce or eliminate our commercialization efforts or our product development programs. The cumulative net loss from our inception through December 31, ~~2022~~ **2023** was approximately $ ~~150~~ **172** million. Net cash used in operations was $ ~~16~~ **13** . ~~2~~ **7** million for the year ended December 31, ~~2022~~ **2023** . Since our inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable. At December 31, ~~2022~~ **2023** , we had cash and cash equivalent balances ~~and short- term investments~~ aggregating $ ~~37~~ **23** . ~~5~~ **1** million, resulting primarily from ~~the~~ **a** 2021 public offering and note issuances pursuant to the 2020 Financing Transaction as discussed in ~~Notes~~ **Note** ~~9 and~~ 7 ~~, respectively,~~ to the consolidated financial statements included elsewhere in this Annual Report. **We also completed a public common stock offering in March 2024 providing net proceeds of approximately $ 14. 0 million.** Our plans for the next twelve months reflect our anticipation of increases in revenues from sales of ~~the ClearPoint system~~ **our hardware products** and related disposable products as a result of greater utilization at existing installed sites and the installation of **our products** ~~the ClearPoint system~~ at new sites, as well as **payments** from **strategic partnerships,** consulting services and sales of systems and disposables to our pharmaceutical partners for gene and stem cell therapy trials. We also anticipate increases over the next twelve months in operating expenses to support the expected increase in revenues, with resulting decreases in loss from operations and in cash flow used in operations. However, there is no assurance that we will be able to achieve anticipated results, and even in the event such results are achieved, we expect to continue to consume cash in operations over at least the next twelve months. As a result of the foregoing, ~~we believe~~ it ~~may~~ **is uncertain whether or not it will** be necessary to seek additional sources of funds from the sale of equity or other debt securities, which likely would result in dilution to existing ownership interests, from the establishment of a credit facility, or from entry into an agreement with a strategic partner or some other form of collaborative relationship. There is no assurance, however, that we will be able to obtain such additional financing on commercially reasonable terms, if at all, and there is no assurance that any additional financing we do obtain will be sufficient to meet our needs. If we are not able to obtain the additional financing on a timely basis, we may be unable to achieve anticipated results, and may not be able to meet other obligations as they become due. An inability to obtain a sufficient amount of additional funding would create substantial doubt as to our ability to continue as a going concern. The funding requirements for our business will depend on many factors, including: • the timing of broader market acceptance and adoption of our ClearPoint platform products and services ; • the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system ; • the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities and other corporate infrastructure ; • the cost and timing of establishing inventories at levels sufficient to support our sales ; • the scope, rate of progress and cost of our research and development activities relating to new products ; • the effect of competing technological and market developments ; • the costs, terms and timing of any future investments or acquisitions, or collaborative, licensing or other arrangements that we may establish ; • the cost and timing of any clinical trials ; • the cost and timing of regulatory filings, clearances and approvals ; and • the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights. Raising additional funds may cause dilution to existing stockholders, restrict our operations, or require us to relinquish proprietary rights. To the extent we raise additional capital through the sale of equity or convertible debt securities, existing ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect such existing stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we secure additional funds through arrangements with a strategic or other collaboration partner, we may have to relinquish valuable rights to our technologies, products or product candidates or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our commercialization and / or product development goals and have a material adverse effect on our business, financial condition, results of operations and prospects. Our cash, cash equivalents and short- term marketable securities are subject to economic risk. The Company may invest its cash, cash equivalents and short- term marketable securities in domestic bank deposits, money market funds, U. S. Government debt securities, corporate debt, and certificates of deposit. Certain types of these investments are subject to general credit, liquidity, market and interest rate risks. In the event these risks caused a decline in value of any of the Company' s investments, it could adversely affect the Company' s financial condition. We **currently, and may in** ~~are subject to risks associated with~~ the ~~upcoming transition from LIBOR~~ **future, have assets held at financial institutions that may exceed the insurance coverage offered by the Federal Deposit Insurance Corporation (" FDIC"), and the loss of such assets could have a negative effect on our operations and liquidity** . ~~Our secured convertible~~ **In early 2023, multiple banks were closed by regulatory agencies and swept into receivership. We currently have our cash and cash equivalents held in deposit in accounts at certain FDIC- insured financial institutions, some of which include amounts in excess of the insurance coverage offered by the FDIC. In the future, we may maintain our cash assets at financial institutions in the United States in amounts that may be in excess of the FDIC insurance limit of** $ **250, 000. Though to** ~~10 million note payable uses the London Interbank Offering Rate~~ **date , we have experienced no loss** ~~(" LIBOR ") as a benchmark for~~ **or lack of access** ~~establishing the interest rate. In March 2021, the U. K. Financial Conduct Authority announced that all LIBOR settings will either cease~~ to ~~be provided by~~ **cash in our operating accounts, in the event of a failure of** any ~~administrator~~ **of these financial institutions where we maintain** ~~or~~ **our deposits** ~~no longer be representative immediately after December 31, 2021 for~~ **or** ~~sterling, euro, Swiss franc and Japanese yen settings, as well as the~~ **other** ~~one- week and~~ **assets, we may incur a loss** ~~two~~ **to the extent such deposits** ~~- month U. S. dollar settings, and immediately after June 30, 2023 for~~ **or assets exceeds**

the **FDIC insurance limitation, which could** ~~remaining U. S. dollar settings. While we~~ have **a material adverse effect upon** ~~not yet incorporated LIBOR- replacement provisions into our applicable note, we will need to do so before June 30, 2023. The discontinuation and replacement of LIBOR or~~ **our liquidity,** ~~any other benchmark rates may have an unpredictable impact on contractual mechanics in the credit markets or cause disruption to the broader~~ financial **condition** ~~markets. Additionally, uncertainty as to the nature of such potential discontinuation~~ and ~~replacement, including that any benchmark may not be the economic equivalent of LIBOR or~~ **our results** ~~not achieve market acceptance similar to LIBOR, may negatively impact the cost~~ of **operations** ~~our variable rate debt~~ . Risks Related to Our Intellectual Property If we, or the third parties from whom we license intellectual property, are unable to secure and maintain patent or other intellectual property protection for the intellectual property covering our marketed products or our product candidates, our ability to compete will be harmed. Our commercial success depends, in part, on obtaining patent and other intellectual property protection for the technologies contained in our products and product candidates. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Our patent position is uncertain and complex, in part, because of our dependence on intellectual property that we license from others. If we, or the third parties from whom we license intellectual property, fail to obtain adequate patent or other intellectual property protection for intellectual property covering our products or product candidates, or if any protection is reduced or eliminated, others could use the intellectual property covering our products or product candidates, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or to which we have rights. U. S. patents and patent applications may be subject to interference proceedings and U. S. patents may be subject to inter partes proceedings (“ IPRs ”), reissue and reexamination proceedings in the United States Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings 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. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, IPRs, reexamination and opposition proceedings may be costly and time consuming, and we, or the third parties from whom we license intellectual property, may be unsuccessful in such proceedings. Thus, any patents that we own or license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may not result in patents being issued or may have claims that do not cover our products or product candidates. Even if any of our pending or future patent applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain. Non- payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the U. S., particularly in the field of medical devices and procedures. Others may assert that our products infringe their intellectual property rights, which may cause us to engage in costly disputes and, if we are not successful in defending ourselves, could also cause us to pay substantial damages and prohibit us from selling our marketed products. There may be U. S. and foreign patents issued to third parties that relate to our business. Some of these patents may be broad enough to cover one or more aspects of our present technologies and / or may cover aspects of our future technologies. We do not know whether any of these patents, if they exist and if asserted, would be held valid, enforceable and infringed. We cannot provide any assurance that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or non- infringement of any third- party patent. The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights, and companies have employed such actions to gain a competitive advantage. If third parties assert infringement or other intellectual property claims against us, our management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages and we may be required to stop selling our products or obtain a license which, if available at all, may require us to pay substantial royalties. We cannot be certain that we will have the financial resources or the substantive arguments to defend our products from infringement or our patents from claims of invalidity or unenforceability, or to defend our products against allegations of infringement of third- party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could negatively impact our business. If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, our ability to successfully commercialize our marketed products and product candidates will be harmed, and we may not be able to operate our business profitably. Our success and ability to compete is dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright, trademark and trade secret law and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties to protect our intellectual property. There can be no assurance that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights. Litigation to enforce our intellectual

property rights in patents, copyrights or trademarks is highly unpredictable, expensive and time consuming and would divert human and monetary resources away from managing our business, all of which could have a material adverse effect on our financial condition and results of operations even if we were to prevail in such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or that they are invalid or unenforceable, and could award attorney fees. Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technologies or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technologies or other information that we regard as proprietary. Additionally, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the U. S. Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technologies, which could substantially impair our ability to compete. We have entered into confidentiality and intellectual property assignment agreements with our employees and consultants as one of the ways we seek to protect our intellectual property and other proprietary technologies. However, these agreements may not be enforceable, or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Our employees and consultants may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our proprietary know- how is expensive and time- consuming, and the outcome is unpredictable. In addition, courts outside the U. S. are sometimes less willing to protect know- how than courts in the U. S. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Failure to obtain or maintain intellectual property protection could adversely affect our competitive business position. **We rely on patent rights and licenses from third parties which are subject to termination or expiration. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products, as our ability to prevent competitors from copying our technology may be limited. Given the amount of time required for the development, testing and regulatory review of potential new medical technologies, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Additionally, should any patent licenses be prematurely terminated for any reason, or if the patents and intellectual property assigned to us or owned by third parties that we have licensed are challenged or defeated, our research efforts could be materially and adversely affected. There is also the related risk that we may not be able to make the required payments under any patent license, in which case we may lose to ability to use one or more of the licensed patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may not be able to protect our intellectual property rights throughout the world. Third parties may attempt to commercialize competitive products in foreign countries where we do not have any patents or patent applications and / or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection. In particular, many countries limit the enforceability of patents against certain 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. Even in foreign jurisdictions that enforce intellectual property rights to the same or a similar extent as do the laws of the United States, uneven enforcement and procedural barriers may exist in such countries, and proceedings to enforce our intellectual property rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not being issued and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.** If we lose access to third- party software that is integrated into our products, our costs could increase and new installations of our products could be delayed, potentially hurting our competitive position. We have received licenses from third parties to certain software that is integrated into the software components of our products. In return, we have agreed to pay license fees and royalties subject to commercial arrangements with such third- party licensors. A loss of any of the licenses could impede our ability to offer and sell our products to customers until equivalent software could be identified, licensed or developed, and integrated into our products. These delays, if they occur, would harm our business, operating results and financial condition. Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others. We rely, in part, upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the

development of our products and technology. These and other licenses may not provide exclusive rights to use such intellectual property and technology, and we may not have intellectual property rights through such licenses in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Our licensors may have relied on third- party consultants or collaborators or on funds from third parties such that our licensors are not in sole and exclusive control or may not be the sole owners of the patents we in- license. This could materially and adversely affect our business, financial condition and results of operations. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in- licenses are terminated, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to larger financial commitments. Any of these events could materially and adversely affect our business, financial condition and results of operations. Risks Related to Legal and Regulatory Compliance We operate in a highly- regulated industry and any failure to comply with the extensive government regulations may subject us to fines, injunctions and other penalties that could harm our business. We are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulations and foreign requirements specific to medical devices are wide ranging and govern, among other things: • design, development and manufacturing; • ~~pre- clinical~~ **preclinical** and clinical testing; • testing, labeling and storage; • product safety; • marketing, sales and distribution; • premarket clearance, authorization, or approval; • recordkeeping procedures; • advertising and promotions; • recalls and field 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; and • product export. We are subject to ongoing regulatory requirements, including: required submissions of safety and other post- market information; manufacturing facility registration and device listing requirements; compliance with medical device current Good Manufacturing Practice regulations, as codified in the QSR; requirements regarding field corrections and removals of our marketed products; reporting of adverse events and certain product malfunctions to regulatory bodies; and numerous recordkeeping requirements. If we or any of our collaborators or suppliers fail to comply with applicable regulatory requirements, a regulatory agency may take action against us, including any of the following sanctions: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • customer notifications or orders for the repair or replacement of our products or refunds; • recall, detention or seizure of our products; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying requests for regulatory approvals of new products or modified products; • withdrawing regulatory submissions that have already been granted; or • refusing to grant export approval for our products. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation, administrative, or executive action, either in the U. S. or abroad. For example, the Biden administration has taken and will continue to take executive actions, some of which could impact us and our business. The implementation of new policies and priorities by **future** ~~the Biden administration~~ **administrations** are unknown and could materially impact the regulation of our products. If executive actions impose constraints on the FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted **. In addition, our biologics and drug delivery business may be subject to regulations and guidance concerning the procurement and use of research animals for research purposes. Such regulations and guidance are evolving and continues to be developed for other areas that impact the biomedical research community on both a national and international basis. Our failure to comply with these regulations and guidance could have a material adverse effect on our business** . Federal legislation and other payment and policy changes may have a material adverse effect on our business. Since enactment of the Affordable Care Act in 2010, there have been a number of legal challenges as well as other legislative and regulatory changes to the healthcare system that could limit the acceptance and availability of our products, which would have an adverse effect on our financial results and business. The full effects of the Affordable Care Act may be unknown until all outstanding legal issues are resolved, the statutory provisions are fully implemented, and CMS, the FDA, and other federal and state agencies issue final applicable regulations or guidance. These developments could result in increased coordination between hospitals and physicians and alignment of financial incentives between hospitals and physicians to control hospital costs. Such payment reform efforts and increased coordination among hospitals and physicians may lead to voluntary reductions in the array of choices currently available to physicians with respect to diagnostic services, medical supplies and equipment, which could result in hospitals reducing the overall number of vendors from which they purchase supplies, equipment and products. The Affordable Care Act may continue to be periodically subject to legal challenges or a continuing political effort to limit its scope. While we do not expect the Biden Administration to modify or repeal the Affordable Care Act, we cannot offer assurances that the political situation regarding the Affordable Care Act will not

change in the future in ways that could have a material adverse effect on our business or results of operations. The Medicare Access and CHIP Reauthorization Act, or the Medicare Access Act, removed the sustainable growth rate or SGR, methodology applicable to fees for physician services. The Medicare Access Act also replaced the previous fee- for- service payment system with a more value- based system. As a result, reimbursements from the Medicare program may be reduced. As noted above, failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used may deter them from purchasing or using our products and will limit our sales growth. The Affordable Care Act also imposes, among other things, an annual excise tax on any entity that manufactures or imports medical devices offered for sale in the U. S. In December 2019, President Trump signed into law a permanent repeal of the medical device tax under the Affordable Care Act, but there is no guarantee that **such repeal** ~~Congress or President Biden~~ will not reverse course in the future. If such an excise tax on sales of our products in the U. S. is enacted, it could have a material adverse effect on our business, results of operations and financial condition **. The Inflation Reduction Act (" IRA"), aimed at curbing inflationary pressures, may have direct and indirect consequences for pharmaceutical and biotech companies in the context of their research and development expenditures. In particular, the IRA measures to control inflation have implications for future drug pricing. Our pharmaceutical and biotech customers rely on predictable pricing to fund research and development efforts. If pricing flexibility is constrained, these companies may limit spending on their pipeline, which may adversely affect the future revenue of our biologics and drug delivery business** . Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives will be implemented at the federal or state level, or the effect any recently promulgated or future legislation or regulation will have on us. However, an expansion in government' s role in the U. S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially. Our products may be subject to product recalls that could harm our reputation, business operating results and financial condition. Likewise, products that are manufactured and sold by third parties and that are needed for procedures in which physicians use our products also may be subject to recalls, which could adversely impact our business, operating results and financial condition. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We may initiate certain voluntary recalls involving our products in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If we determine that certain of those recalls do not require notification to the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement actions against us, which could impair our ability to produce our products in a cost- effective and timely manner to meet our customers' demands. Regulatory investigations or product recalls could also result in our incurring substantial costs, losing revenues and implementing a change in the design, manufacturing process or the indications for which our products may be used, each of which would harm our business. In addition, products that are manufactured and sold by other companies and that are needed for procedures in which physicians use ClearPoint devices also could become subject to a recall. ClearPoint devices are designed to enable a range of minimally invasive procedures in the brain. Those procedures involve insertion of a catheter, probe, electrode or other similar device into a target region of the brain, and most of those devices are manufactured and sold by other companies. Any of those devices may become the subject of a recall, whether required by the FDA or a foreign governmental body or initiated by the third- party manufacturer. The shortage or absence of any of those devices in the marketplace could adversely impact the number of procedures performed by physicians using our ClearPoint devices, which would adversely impact our financial condition and results of operations. If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Under the FDA' s Medical Device Reporting regulations, we are required to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our products malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In the future, we may experience events that may require reporting to the FDA pursuant to the medical device reporting regulations. In addition, all manufacturers placing medical devices in EU markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. Any adverse event involving our products could result in future 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 defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. In addition, failure to report such adverse events to appropriate government authorities on a timely basis, or at all, could result in an enforcement action against us. We may incur significant liability if it is determined that we are promoting off- label uses of our products in violation of federal and state regulations in the U. S. or elsewhere. We have obtained 510 (k) clearance of the products that we commercialize for defined indications. Promotion or marketing of our products for any indications for use other than that cleared by the FDA would be considered off- label use. Under the federal Food, Drug, and Cosmetic Act and other similar laws, we are prohibited from labeling or promoting our products, or training physicians, for such off- label uses. The FDA defines labeling to include not only

the physical label attached to the product, but also items accompanying the product. This definition also includes items as diverse as materials that appear on a company' s website. As a result, we are not permitted to promote off- label uses of our products, whether on our website, in product brochures or in customer communications. However, although manufacturers are not permitted to promote for off- label uses, in their practice of medicine, physicians may lawfully choose to use medical devices for off- label uses. Therefore, a physician could use our products for uses not covered by the cleared labeling. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off- label uses and the promotion of products for which marketing clearance or approval has not been obtained. If the FDA determines that our promotional materials or training constitutes promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. We could be enjoined from selling some or all of our products for any unapproved uses. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and market adoption of our products would be impaired. In addition, the off- label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management' s attention and result in substantial damage awards against us. If we or our third- party suppliers fail to comply with the FDA' s QSR or any applicable state equivalent, our manufacturing operations could be interrupted, and our potential product sales and operating results could suffer. We and some of our third- party suppliers are required to comply with the FDA' s QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products and product candidates. We and our suppliers will also be subject to the regulations of foreign jurisdictions regarding the manufacturing process to the extent we market our products in these jurisdictions. The FDA enforces the QSR through periodic and unannounced inspections of manufacturing facilities. Our facilities were last ~~inspected for QSR compliance~~ **subject to an ISO 13485 surveillance audit and MDSAP surveillance audit** in ~~February~~ **April** ~~2021~~ **2023** . We anticipate that we and certain of our third- party suppliers will be subject to future inspections. The failure by us or one of our third- party suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations, could result in enforcement actions against us, which could impair our ability to produce our products in a cost- effective and timely manner to meet our customers' demands. If we fail to comply with the FDA' s QSR or any applicable state equivalent, we would be required to incur the costs and take the actions necessary to bring our operations into compliance, which may have a negative impact on our future sales and our ability to generate a profit ~~. We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities. The manufacture of certain of our products and the handling of materials used in the product testing process involve the use of biological, hazardous and / or radioactive materials and wastes. Our business and facilities and those of our suppliers are subject to foreign, federal, state, and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling, and disposal of, and exposure to, such materials and wastes. Further, we may be required to comply with related disclosure requirements as a public company, In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third- party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations, and financial condition~~ . We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws. Although we do not provide healthcare services or receive payments directly from Medicare, Medicaid or other third- party payors for our products or the procedures in which our products may be used, many state and federal healthcare laws and regulations governing financial relationships between medical device companies and healthcare providers apply to our business and we could be subject to enforcement by both the federal government, private whistleblowers and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include: • The federal healthcare programs' Anti- Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or providing any kickback, bribe or other remuneration, directly or indirectly, in exchange for or to induce the purchase, lease or order, or arranging for or recommending of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. • Federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other federally- funded healthcare programs that are false or fraudulent, or are for items or services not provided as claimed, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices. Changes to the federal false claims law enacted as part of the Affordable Care Act will likely increase the number of whistleblower cases brought against providers and suppliers of health care items and services. • The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services. • State and foreign law equivalents of each of the above federal laws, such as: (i) anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers ; and (ii) the Foreign Corrupt Practices Act, which may apply to interactions with foreign government officials, including physician employees of a foreign government entity, by our employees and third- party business partners. • The Affordable Care Act, which imposes certain reporting obligations on manufacturers of drugs, devices and biologics. Specifically, such manufacturers are required to report

payments or other transfers of value to or on behalf of physicians, physician assistants, certain types of advance care nurses or teaching hospitals by such manufacturers, as well as any ownership or investment interest held by physicians in such manufacturers. Violations of the reporting requirements are subject to civil monetary penalties. • The Affordable Care Act also grants the Office of Inspector General additional authority to obtain information from any individual or entity to validate claims for payment or to evaluate the economy, efficiency or effectiveness of the Medicare and Medicaid programs, expands the permissible exclusion authority to include any false statements or misrepresentations of material facts, enhances the civil monetary penalties for false statements or misrepresentation of material facts, and enhances the Federal Sentencing Guidelines for those convicted of federal healthcare offenses. The medical device industry has been under heightened scrutiny as the subject of government investigations and government enforcement or private whistleblower actions under the Anti- Kickback Statute and the False Claims Act involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including specifically arrangements with physician consultants. We may from time to time have agreements with physicians that could be scrutinized or could be subject to reporting requirements in the future, including consulting contracts in which we compensate physicians for various services, which could include: • providing training and other similar services on the proper use of our products; • advising us with respect to the commercialization of products in their respective fields; • keeping us informed of new developments in their respective fields of practice; • advising us on our research and development projects related to their respective fields; • advising us on improvements to methods, processes and devices related to their respective fields (such as advice on the development of prototype devices); and • assisting us with the technical evaluation of our methods, processes and devices related to their respective fields. The Affordable Care Act mandates increased transparency of arrangements between physicians and medical device companies. We believe that this increased transparency may also result in a heightened level of government scrutiny of the relationships between physicians and medical device companies. While we believe that all of our arrangements with physicians comply with applicable law, the increased level of scrutiny, coupled with the expanded enforcement tools available to the government under the Affordable Care Act, may increase the likelihood of a governmental investigation. If we become subject to such an investigation, our business and operations would be adversely affected even if we ultimately prevail because the cost of defending such investigation would be substantial. Moreover, companies subject to governmental investigations could lose both overall market value and market share during the course of the investigation. In addition, we may provide customers with information on products that could be deemed to influence their coding or billing practices, and may have sales, marketing or other arrangements with hospitals and other providers that could also be the subject of scrutiny under these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If the physicians or other providers or entities with which we do business are found to be non- compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business. We are subject to various laws protecting the confidentiality and security of certain personal information, and our failure to comply could result in penalties and reputational damage. We are subject to various laws and regulations protecting the confidentiality and security of certain patient health information, and our failure to comply with such laws and regulations could result in penalties and reputational damage. Within the U. S., numerous federal and state laws governing the collection, use, disclosure and storage of personal information may apply to us, including, without limitation, HIPAA, state data privacy laws (for example, the California Consumer Privacy Act and the California Privacy Rights Act), state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws. In addition, in certain cases, we may be a business associate of our HIPAA covered entity customers by virtue of receiving individually identifiable health information (referred to as " Protected Health Information " or " PHI ") from these customers. In these business associate relationships, we must comply with applicable HIPAA requirements, state data privacy and security requirements, and the contractual terms of our business associate agreements that govern its permitted uses and disclosures of PHI received from the covered entity counterparty. Our failure to comply with any of these laws may result in criminal and civil liability. Enforcement actions can be costly and interrupt regular operations which may adversely affect our business. Outside the U. S., numerous countries in which we operate, manufacture, and sell our products have, or are developing, laws protecting data privacy and the confidentiality of certain personal data. For example, the EU General Data Protection Regulation (" GDPR ") ~~, which became effective on May 25, 2018,~~ introduced new data protection requirements in the European Economic Area and substantial fines for violations of the data protection rules. The GDPR applies extraterritorially, and we may be subject to the GDPR because of our **EU subsidiaries and** potential data processing activities that involve the personal data of individuals located in the EU, such as in connection with any EU customers, EU clinical trials or related to any employees in the EU. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data, which could cause our costs of compliance to increase, potentially leading to harm to our business and financial condition. Globally, the legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues that may affect our business. There is a degree of uncertainty associated with the legal and regulatory environment around privacy and data protection laws, which continue to develop in ways we cannot predict. Privacy and data protection laws may be interpreted and applied inconsistently from country to country and impose inconsistent or conflicting requirements. Varying jurisdictional requirements could increase the costs and complexity of compliance or require us to change our business practices in a manner adverse to our business. A determination that we have violated privacy or data protection

laws could result in significant damage awards, fines and other penalties that could, individually or in the aggregate, materially harm our business and reputation. Our Fourth Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the U. S. 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 Fourth Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum (to the fullest extent permitted by law, and subject to applicable jurisdictional requirements) for claims in the right of the corporation that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery of the State of Delaware. Our Fourth Amended and Restated Bylaws further provide that the federal district courts of the U. S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933. 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 lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive- forum provision in our Fourth Amended and Restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Risks Related to Our Common Stock The market price of our common stock may be volatile, and a stockholder may not be able to resell their shares at or above the price at which the shares were purchased. Companies trading in the stock market in general have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The market price of our common stock may be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following: • Failure to successfully develop our products ; • Changes in laws or regulations applicable to future products ; • Inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices ; • Adverse regulatory decisions ; • Introduction of new products, services or technologies by our competitors ; • Failure to meet or exceed financial projections we may provide to the public ; • Inability to obtain additional funding; • Failure to meet or exceed the financial projections of the investment community ; • Disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies ; • Additions or departures of key personnel ; • Significant lawsuits, including patent or stockholder litigation ; • Changes in the market valuations of similar companies ; • Purchases and sales of our common stock resulting from, related to or arising out of (i) recent stock run- ups or recent divergences in valuations relative to those seen during traditional markets, (ii) high short interest or reported short squeezes, or (iii) reports of strong and atypical retail investor interest (whether on social media or otherwise); • Sales of our common stock by us or our stockholders in the future ; and • Trading volume of our common stock. Our ability to use net operating losses to offset future taxable income may be subject to certain limitations. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to substantial limitations arising from previous ownership changes. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U. S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U. S. federal taxable income necessary to utilize our NOLs. We have not paid dividends in the past and do not expect to pay dividends in the future. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our Board of Directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payments of dividends present in any of our future debt agreements and other factors our Board of Directors may deem relevant. If we do not pay dividends, a return on our stockholders' investment will only occur if our stock price appreciates. Anti- takeover provisions in our certificate of incorporation, bylaws and Delaware law could prevent or delay a change in control. We have ~~200~~ **90** , 000, 000 shares of common stock authorized, and ~~24~~ **26** , ~~609~~ **976** , ~~284~~ **289** shares outstanding as of ~~February 15~~ **March 5** , ~~2023~~ **2024** . As a result, our Board will be able to issue a substantial number of additional shares of common stock, without seeking stockholder approval. In addition, provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, may discourage, delay or prevent a merger, acquisition or change of control. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions: • permit our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control; • provide that the authorized number of directors may be changed only by resolution of the Board of Directors; • provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; • require that any action to be taken by our stockholders must be effected at a duly called annual or special

meeting of stockholders and not be taken by written consent; • provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder' s notice; • do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); • provide that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and • provide that stockholders will be permitted to amend our bylaws only upon receiving at least 66 2 / 3 % of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any broad range of business combinations with any stockholder who owns, or at any time in the last three years owned, 15 % or more of our outstanding voting stock, for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price. We publicly provide financial guidance about our business and future operating results. In developing this guidance, our management makes certain assumptions and judgments about our future operating performance, including projected hiring of personnel, continued increase of our revenue, and continued stability of the macro- economic environment in our key markets. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors, or other interested parties, the market price of our common stock could decline. Securities analysts may not continue, or additional securities analysts may not initiate, coverage for our common stock or may issue negative reports. This may have a negative impact on the market price of our common stock. Securities analysts provide research coverage of our common stock. Some analysts may publish statements that do not portray our technology, products or procedures using our product in a positive light. If we are unable to educate those who publicize such reports about the benefits we believe our business provides, or if one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If sufficient securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. It may be difficult for companies such as ours, with smaller market capitalizations, to attract and maintain sufficient independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock. We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price. General Risk Factors Damage to our reputation could harm our businesses, including our competitive position and business prospects. Our ability to attract and retain customers, suppliers, investors and employees is impacted by our reputation. Harm to our reputation can arise from various sources, including employee misconduct, security and privacy breaches, unethical behavior, litigation or regulatory outcomes, and scrutiny in connection with federal and state healthcare fraud and abuse laws and regulations. Such harm could also, among other consequences, increase the size and number of litigation claims and damages asserted or subject us to enforcement actions, fines and penalties and cause us to incur related costs and expenses. **The preclinical services that our biologics and drug delivery business provides to our customers are essential to drug discovery and development processes, and a significant number of these services are mandated by law. Notwithstanding, certain special interest groups categorically object to the use of animals for valid research purposes. Historically, research activities with animals have been the subject of adverse attention, including shareholder proposals and attempts to disrupt such services, impacting the industry. This may, in the future, include periodic demonstrations near facilities operated or utilized by us. Any negative attention, threats, acts of vandalism or legal action directed against our preclinical service activities, or our third- party service providers could harm our reputation and impair our ability to operate our business efficiently.** We could become subject to product liability or professional liability claims that could be expensive, divert management' s attention and harm our business. Our business exposes us to potential product liability risks that are inherent in the manufacturing, marketing and sale of medical devices. We may be held liable if our products cause injury or death or are found otherwise unsuitable or defective during usage. Our ClearPoint system, ClearPoint Prism Neuro Laser Therapy System, and other products may incorporate mechanical and electrical parts, complex computer software and other sophisticated components, any of which can have defective or inferior parts or contain defects, errors or failures. Complex computer software is particularly vulnerable to errors and failures, especially when first introduced. Because our products are designed to be used to perform complex surgical procedures, defects could result in a number of complications, some of which could be serious and could harm or kill patients. The adverse publicity resulting from any of these events could cause physicians or hospitals to review and potentially terminate their relationships with us. We may also be subject to professional liability for errors in the clinical support that we provide to clinicians in connection with our products or for a misunderstanding of, or inappropriate reliance upon, the information we provide. The medical device industry has historically been subject to extensive litigation over product liability and professional liability claims. A product liability or professional liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Although we maintain liability insurance that we believe is appropriate, this insurance coverage

is subject to deductibles and coverage limitations, and may not be adequate to protect us against any future liability claims. Additionally, we may be unable to maintain our existing liability insurance in the future at satisfactory rates or in adequate amounts. A liability claim, regardless of its merit or eventual outcome, could result in: • decreased demand for our products; • injury to our reputation; • diversion of management' s attention; • significant costs of related litigation; • payment of substantial monetary awards by us; • product recalls or market withdrawals; • a change in the design, manufacturing process or the indications for which our marketed products may be used; • loss of revenue; and • an inability to commercialize product candidates. Our operations are vulnerable to interruption or loss due to natural disasters, power loss and other events beyond our control, which would adversely affect our business. To date, we do not have redundant facilities. We conduct many of our activities, including research and development, component processing, final assembly, packaging and distribution activities for most of our products, at our facility located in Southern California, which is a seismically active area that has experienced major earthquakes in the past, as well as other natural disasters, including wildfires. We have taken precautions to safeguard our facility, including obtaining business interruption insurance. However, any future natural disaster, such as an earthquake or a wildfire, pandemics ~~, such as the COVID- 19 pandemic~~ , or other unanticipated catastrophes, such as telecommunications failures, cyberattacks, or terrorist attacks, at any of the locations in which we or our key partners, suppliers and customers do business, could significantly disrupt our operations, and delay or prevent product assembly and shipment during the time required to repair, rebuild or replace our facility, which could be lengthy and result in significant expenses. Furthermore, the insurance coverage we maintain may not be adequate to cover our losses in any particular case or continue to be available at commercially reasonable rates and terms. In addition, our facility may be subject to shortages of electrical power, natural gas, water and other energy supplies. Any future shortage or conservation measure could disrupt our operations and cause expense, thus adversely affecting our business and financial results. The requirements of being a public company may strain our resources and distract management. As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (" Exchange Act "), and the Sarbanes- Oxley Act of 2002 (" Sarbanes- Oxley Act "). We are also subject to certain provisions of the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 (" Dodd- Frank Act "). The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Dodd- Frank Act requires the SEC to adopt certain rules and regulations relating to our public disclosures, corporate governance and executive compensation, among other things, and such rules and regulations require significant attention from management. Compliance with all of these laws, rules and regulations may from time to time divert management' s attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. The Sarbanes- Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting and management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. To maintain the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight is required. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the SEC. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, or attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management' s attention.