Risk Factors Comparison 2024-03-29 to 2023-03-10 Form: 10-K

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

Our business is subject to numerous risks..... all or part of your investment. Risks Related to Our Business and Operations We have incurred losses in the past, our financial statements have been prepared on a going concern basis and we may be unable to achieve or sustain profitability in the future. To date, we have financed our operations primarily through the issuance of public and private equity and convertible notes. We have devoted substantially all of our resources to research and development, creating the infrastructure for a publicly traded medical device company, preparing for our national commercial launch, and clinical and regulatory matters for our products. There can be no assurances that we will be able to generate sufficient revenue from our existing products or from any future product candidates to transition to profitability and generate consistent positive cash flows. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance, and commercialize our existing and new products and incur additional operating and reporting costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives. Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the fiscal year ended, December 31, ~~2022~~ **2023**, describing the existence of substantial doubt about our ability to continue as a going concern. Our expected future capital requirements may depend on many factors including expanding our clinician base, increasing the rate at which we train clinicians, the number of additional clinical papers initiated, and the timing and extent of spending on the development of our technology to increase our product offerings. We may need additional funding to fund our operations but additional funds may not be available to us on acceptable terms on a timely basis, if at all. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations ~~. Epidemic diseases including COVID- 19, or the perception of their effects could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Outbreaks of infectious diseases, such as COVID- 19, could divert medical resources and priorities towards the treatment of that disease. An outbreak of an infectious disease, or continued escalation of the outbreak of COVID- 19 could also negatively affect hospital admission rates and the decision by patients to undergo elective surgery, which could decrease demand for procedures using The CATAMARAN System and cause other disruptions to our business. Business disruptions could include disruptions or restrictions on our ability to travel or to distribute our products, government orders suspending the performance of elective surgical procedures such as The CATAMARAN System, inability of our customers to meet their financial commitments due to strain on the healthcare system, as well as temporary closures of our facilities or the facilities of our suppliers and their contract manufacturers, and a reduction in the business hours of hospitals and ambulatory surgery centers. Any disruption of our contract manufacturers or our customers would likely impact our sales and operating results. In addition, a significant outbreak of an infectious disease in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products. Any of these events could negatively impact the number of procedures using The CATAMARAN System that are performed and have a material adverse effect on our business, financial condition, results of operations, or cash flows. 20 COVID- 19 may have an adverse impact on the timing and success of the commercialization of The CATAMARAN System and our future operations as a result of preventive and precautionary measures that we may find necessary to take. There are numerous uncertainties associated with this COVID- 19 outbreak, including the number of individuals who will become infected, the level of resistance to taking vaccines by significant portions of the population in the United States, the extent of the protective and preventative measures that have been put in place by both governmental entities and other businesses and those that may be put in place in the future, the effect that general availability of vaccines, testing for COVID- 19 and antibodies will enable relaxation of protective measures for a subset of the population, and numerous other uncertainties. We intend to continue to execute on our product development and strategic plans during the COVID- 19 outbreak. However, the aforementioned uncertainties may result in delays or modifications to our product development and strategic plans. In addition, the COVID- 19 pandemic has adversely affected, and may continue to adversely affect, the economies and financial markets of many countries, which may result in a period of regional, national, and global economic slowdown or regional, national, or global recessions that could curtail or delay spending by hospitals and affect demand for our products as well as increased risk of customer defaults or delays in payments. These market disruptions could impair our ability to raise capital, should our business experience a prolonged period of reduced revenue requiring additional capital to sustain the business. COVID- 19 and the current financial, economic, and capital markets environment, and future developments in these~~

~~and other areas present material uncertainty and risk with respect to our performance, financial condition, results of operations, and cash flows. Due to the uncertain scope and duration of the pandemic and uncertain timing of global recovery and economic normalization, we are unable to estimate the long- term impacts on our operations and financial results. The existence and further duration of the COVID- 19 pandemic may also further exacerbate certain of the risks described below~~ . Practice trends or other factors, including the COVID- 19 pandemic, may cause procedures to shift from the hospital environment to ambulatory surgical centers (" ASCs "), where pressure on the prices of our products is generally more acute. To protect health care professionals involved in surgical care and their patients, we anticipate that more outpatient eligible procedures will be performed in ASCs during the COVID- 19 pandemic, and as its acuity declines and the healthcare system returns to a more normalized state. Since patients do not stay overnight in ASCs and COVID- 19 patients would not otherwise be treated in ASCs, it is likely that the ASC will be viewed as a safer site of service for patients and health care providers, where the risk of transmission of ~~the novel coronavirus~~ **COVID- 19** can be more effectively controlled. Because ASC facility fee reimbursement is typically less than facility fee reimbursement for hospitals, we typically experience more pressure on the pricing of our products by ASCs than by hospitals, and the average price for which we sell our products to ASCs is less than the average prices we charge to hospitals. An accelerated shift of procedures using our products to ASCs as a result of the COVID- 19 pandemic could adversely impact the average selling prices of our products and our revenues could suffer as a result. If hospitals, clinicians, and other healthcare providers are unable to obtain coverage and reimbursement from third- party payors for procedures performed using our products, adoption of our products may be delayed, and it is unlikely that they will gain further acceptance. Growing sales of our product depends on the availability of adequate coverage and reimbursement from third- party payors, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs. Hospitals, clinicians, and other healthcare providers that purchase or use medical devices generally rely on third- party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices. Adequate coverage and reimbursement for procedures performed with our products is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis if third- party payors deny coverage, continue to deny coverage or reduce their current levels of payment, or if our costs for the product increase faster than increases in reimbursement levels. Many private payors refer to coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, as guidelines for setting their coverage and reimbursement policies. By June 30, 2016, all Medicare Administrative Contractors were regularly reimbursing for minimally invasive and / or open SI- Joint fusion. Private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures performed with our products. Private commercial payors have been slower to adopt positive coverage policies for minimally invasive and / or open SI- Joint fusion, and many private payors still have policies that treat the procedure as experimental or investigational and do not regularly reimburse for the procedure. Future action by CMS or third- party payors may further reduce the availability of payments to physicians, outpatient surgery centers, and / or hospitals for procedures using our products. The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Payors are imposing lower payment rates and negotiating reduced contract rates with service providers and being increasingly selective about the technologies and procedures they choose to cover. There can be no guarantee that we will be able to provide the scientific and clinical data necessary to overcome these policies. Payors may adopt policies in the future restricting access to medical technologies like ours and / or the procedures performed using such technologies. Therefore, we cannot be certain that the procedures performed with each of our products will be reimbursed. There can be no guarantee that, should we introduce additional products in the future, payors will cover those products or the procedures in which they are used. ~~21~~ If the reimbursement provided by third- party payors to hospitals, clinicians, and other healthcare providers for procedures performed using our products is insufficient, adoption and use of our products and the prices paid for our implants may decline. When a Tenon procedure utilizing ~~The CATAMARAN~~ **the Catamaran** System is performed, both the clinician and the healthcare facility, a hospital (inpatient or outpatient clinic), submit claims for reimbursement to the patient' s insurer. Generally, the facility obtains a lump sum payment, or facility fee, for SI- Joint fusions. Our products are purchased by the facility, along with other supplies used in the procedure. The facility must also pay for its own fixed costs of operation, including certain operating room personnel involved in the procedure, and other medical services care. If these costs exceed the facility reimbursement, the facility' s managers may discourage or restrict clinicians from performing the procedure in the facility or using certain technologies, such as ~~The CATAMARAN~~ **the Catamaran** System, to perform the procedure. The Medicare 2022 national average hospital inpatient payment ranges from approximately $ 25, 000 to approximately $ 59, 000 depending on the procedural approach and the presence of Complication and Comorbidity (CC) / Major Complication and Comorbidity (MCC). The Medicare 2022 national average hospital outpatient clinic payment is $ 21, 897. We believe that insurer payments to facilities are generally adequate for these facilities to offer ~~The CATAMARAN~~ **the Catamaran** System. However, there can be no guarantee that these facility payments will not decline in the future. The number of procedures performed, and the prices paid for our implants may in the future decline if payments to facilities for SI- Joint fusions decline. Clinicians are reimbursed separately for their professional time and effort to perform a surgical procedure. Depending on the surgical approach, the incision size, type and extent of imaging guidance, indication for procedure, and the insurer, ~~The CATAMARAN~~ **the Catamaran** System procedure may be reported by the clinician using any one of the applicable following CPT ® codes 27279, 27280, 27299. The Medicare 2022 national average payment for CPT ® 27279 is $ 807 and $ 1, 325 for 27280. CPT ® 27299 has no national valuation. Clinicians, however, can present a crosswalk to another procedure believed to be fairly equivalent and / or comparison to a code for which there is an existing valuation. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. Similar to Medicaid, many private payors' coverage and payment may differ from one payer to another as well. We believe that

some clinicians view the current Medicare reimbursement amount as insufficient for the procedure, given the work effort involved with the procedure, including the time to diagnose the patient and obtain prior authorization from the patient' s health insurer when necessary. Many private payors require extensive documentation of a multi- step diagnosis before authorizing SI- Joint fusion for a patient. We believe that some private payors apply their own coverage policies and criteria inconsistently, and clinicians may experience difficulties in securing approval and coverage for sacroiliac fusion procedures. Additionally, many private payors limit coverage for open SI- Joint fusion to trauma, tumors or extensive spine fusion procedures involving multiple levels. The perception by physicians that the reimbursement for SI- Joint fusion is insufficient to compensate them for the work required, including diagnosis, documentation, obtaining payor approval for the procedure, and burden on their office staff, may negatively affect the number of procedures performed and may therefore impede the growth of our revenues or cause them to decline. We may not be able to convince physicians that ~~The CATAMARAN~~ **the Catamaran** System is an attractive alternative to our competitors' products and that our procedure is an attractive alternative to existing surgical and non- surgical treatments of the SI- Joint. Clinicians play the primary role in determining the course of treatment in consultation with their patients and, ultimately, the product that will be used to treat a patient. In order for us to sell ~~The CATAMARAN~~ **the Catamaran** System successfully, we must convince clinicians through education and training that treatment with ~~The CATAMARAN~~ **the Catamaran** System is beneficial, safe, and cost- effective for patients as compared to our competitors' products. If we are not successful in convincing clinicians of the merits of ~~The CATAMARAN~~ **the Catamaran** System, they may not use our product, and we will be unable to increase our sales and achieve or grow profitability. ~~22~~ Historically, most spine clinicians did not include SI- Joint pain in their diagnostic work- up because they did not have an adequate surgical procedure to perform for patients diagnosed with the condition. As a result, some patients with lower back pain resulting from SI- Joint dysfunction are misdiagnosed. We believe that educating clinicians and other healthcare professionals about the clinical merits and patient benefits of ~~The CATAMARAN~~ **the Catamaran** System is an important element of our growth. If we fail to effectively educate clinicians and other medical professionals, they may not include a SI- Joint evaluation as part of their diagnosis and, as a result, those patients may continue to receive unnecessary or only non- surgical treatment. Clinicians may also hesitate to change their medical treatment practices for other reasons, including the following: ● lack of experience with minimally invasive procedures; ● perceived liability risks generally associated with the use of new products and procedures; ● costs associated with the purchase of new products; and ● time commitment that may be required for training. Furthermore, we believe clinicians may not widely adopt ~~The CATAMARAN~~ **the Catamaran** System unless they determine, based on experience, clinical data, and published peer- reviewed publications, that surgical intervention provides benefits or is an attractive alternative to non- surgical treatments of SI- Joint dysfunction. In addition, we believe support of our products relies heavily on long- term data showing the benefits of using our product. If we are unable to provide that data, clinicians may not use our product. In such circumstances, we may not achieve expected sales and may be unable to achieve profitability. Clinicians and payors may not find our clinical evidence to be compelling, which could limit our sales, and on- going and future research may prove our product to be less safe and effective than initially anticipated. All of the component parts of ~~The CATAMARAN~~ **the Catamaran** System have either received premarket clearance under Section 510 (k) of the U. S. federal Food, Drug, and Cosmetic Act, or FDCA, or are exempt from premarket review. The 510 (k) clearance process of the U. S. Food and Drug Administration, or FDA, requires us to document that our product is " substantially equivalent " to another 510 (k)- cleared product. The 510 (k) process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes, such as a premarket approval, or PMA, and does not usually require pre- clinical or clinical studies. Additionally, to date, we have not been required to complete clinical studies in connection with the sale of our product. For these reasons, clinicians may be slow to adopt our product, third- party payors may be slow to provide coverage, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our product does not improve patient outcomes. Such results would slow the adoption of our product by clinicians, significantly reduce our ability to achieve expected sales, and could prevent us from achieving profitability. Moreover, if future results and experience indicate that our product causes unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension, or withdrawal of FDA clearance. Pricing pressure from our competitors, changes in third- party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the proliferation of " physician- owned distributorships " may impact our ability to sell our product at prices necessary to support our current business strategies. If competitive forces drive down the prices we are able to charge for our product, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business. The SI- Joint fusion market has attracted numerous new companies and technologies. As a result of this increased competition, we believe there will be continued and increased pricing pressure, resulting in lower gross margins, with respect to our product. Even to the extent our product and procedures using our product are currently covered and reimbursed by third- party private and public payors, adverse changes in coverage and reimbursement policies that affect our product, discounts, and number of implants used may also drive our prices down and harm our ability to market and sell our product. We are unable to predict what changes will be made to the reimbursement methodologies used by third- party payors. We cannot be certain that under current and future payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, the cost of our product will be justified and incorporated into the overall cost of the procedure. In addition, to the extent there is a shift from inpatient setting to outpatient settings, we may experience pricing pressure and a reduction in the number of ~~The CATAMARAN~~ **the Catamaran** System procedures performed. ~~23Consolidation~~ -- **Consolidation** in the healthcare industry, including both third- party payors and healthcare providers, could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations, or financial condition. Because healthcare costs have risen significantly over the past several years, numerous initiatives and reforms initiated by legislators, regulators, and third- party payors to curb

these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third- party coverage, and reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the price of our product, and adversely impact our business, results of operations, or financial condition. As we continue to expand into international markets, we will face similar risks relating to adverse changes in coverage and reimbursement procedures and policies in those markets. We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow. The ~~CATAMARAN~~ **Catamaran** System is subject to intense competition. Many of our competitors are major medical device companies that have substantially greater financial, technical, and marketing resources than we do, and they may succeed in developing products that would render our product obsolete or non- competitive. In addition, many of these competitors have significantly longer operating histories and more established reputations than we do. Our field is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third- party payors, and are safer, less invasive, and more effective than alternatives available for similar purposes as demonstrated in peer- reviewed clinical publications. Because of the size of the potential market, we anticipate that other companies will dedicate significant resources to developing competing products. In the United States, we believe that our primary competitors are currently SI- bone, Inc., Globus Medical, Inc., Medtronic plc, XTant Medical Holdings, Inc., and RTI Surgical, Inc. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of the SI- Joint that compete directly or indirectly with our product. If alternative treatments are, or are perceived to be, superior to our product, sales of our product and our results of operations could be negatively affected. Some of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies. These competitors may enjoy several competitive advantages over us, including: ● greater financial, human, and other resources for product research and development, sales and marketing, and legal matters; ● significantly greater name recognition; ● established relationships with clinicians, hospitals, and other healthcare providers; ● large and established sales and marketing and distribution networks; ● greater experience in obtaining and maintaining domestic and international regulatory clearances or approvals, or CE Certificates of Conformity for products and product enhancements; ● more expansive portfolios of intellectual property rights; and ● greater ability to cross- sell their products or to incentivize hospitals or clinicians to use their products. New participants have increasingly entered the medical device industry. Many of these new competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our product or that are alternatives to our existing or planned products may make it difficult to differentiate the benefits of our product over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our product and pricing in the market generally. As a result, without the timely introduction of new products and enhancements, our product may become obsolete over time. If we are unable to develop innovative new products, maintain competitive pricing, and offer products that clinicians and other physicians perceive to be as reliable as those of our competitors, our sales or margins could decrease, thereby harming our business. ~~24~~ We currently manufacture (through third parties) and sell products used in a single procedure, which could negatively affect our operations and financial condition. Presently we do not sell any products other than ~~The CATAMARAN~~ **the Catamaran** System and related tools and instruments. Therefore, we are solely dependent on widespread market adoption of ~~The CATAMARAN~~ **the Catamaran** System and we will continue to be dependent on the success of this single product for the foreseeable future. There can be no assurance that ~~The CATAMARAN~~ **the Catamaran** System will gain a substantial degree of market acceptance among clinicians, patients or healthcare providers. Our failure to successfully increase sales of ~~The CATAMARAN~~ **the Catamaran** System or any other event impeding our ability to sell ~~The CATAMARAN~~ **the Catamaran** System, would result in a material adverse effect on our results of operations, financial condition and continuing operations. We have a limited operating history and may face difficulties encountered by early- stage companies in new and rapidly evolving markets. Even though we were formed in 2012 we have just built the infrastructure necessary to commercially launch ~~The CATAMARAN~~ **the Catamaran** System. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. In assessing our prospects, you must consider the risks and difficulties frequently encountered by early- stage companies in new and rapidly evolving markets, particularly companies engaged in the development and sales of medical devices. These risks include our inability to: ● obtain coverage by third- party, private, and government payors; ● establish and increase awareness of our brand and strengthen customer loyalty; ● attract and retain qualified personnel; ● find and develop relationships with contract manufacturers that can manufacture the necessary volume of product; ● manage our independent sales representatives to achieve our sales growth objectives; ● commercialize new products and enhance our existing product; ● manage rapidly changing and expanding operations; ● implement and successfully execute our business and marketing strategy; ● respond effectively to competitive pressures and developments. We can also be negatively affected by general economic conditions. Because of our limited operating history, we may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful. Our sales volumes and our operating results may fluctuate over the course of the year. Since we had our first sales in April 2021 and our official national launch commenced in October 2022, we have limited history

with respect to how rapidly adoption of ~~The CATAMARAN~~ **the Catamaran** System will occur. Sales growth could be slower than we have projected. Our sales and results of operations will be affected by numerous factors, including, among other things: ● payor coverage and reimbursement; ● maintaining our training schedule with clinicians; ● the number of procedures performed in the quarter and our ability to drive increased sales of our product; ● our ability to identify and sign- up independent sales representatives and their performance; ● pricing pressure applicable to our product, including adverse third- party coverage and reimbursement outcomes; ● timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; ~~25~~ ● our ability to find and develop relationships with contract manufacturers and their ability to timely provide us with an adequate supply of products; ● the evolving product offerings of our competitors; ● the demand for, and pricing of, our product and the products of our competitors; ● factors that may affect the sale of our product, including seasonality and budgets of our customers; ● ability of clinicians to do our procedure given possible COVID restrictions; ● interruption in the manufacturing or distribution of our product; ● the effect of competing technological, industry and market developments; ● our ability to expand the geographic reach of our sales and marketing efforts; ● the costs of maintaining adequate insurance coverage, including product liability insurance; ● the availability and cost of components and materials needed by our contract manufacturers; ● the number of selling days in the quarter; and ● impairment and other special charges. Some of the products we may seek to develop and introduce in the future will require FDA clearance or approval before commercialization in the United States. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. Quarterly comparisons of our financial results may not always be meaningful and should not be relied upon as an indication of our future performance. If we do not successfully implement our business strategy, our business and results of operations will be adversely affected. Our business strategy was based on assumptions about the market that might prove wrong. We believe that various demographics and industry- specific trends will help drive growth in the market and our business, but these demographics and trends have been and will continue to be uncertain. Actual demand for our product could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternative treatments to those offered by our product gains widespread acceptance. Also, our strategy of focusing exclusively on the SI- Joint market may limit our ability to grow. In addition, in order to increase our sales, we will need to identify and contract with independent sales representatives in existing and new regions as well, and in the future, commercialize new products. Moreover, we may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors not currently foreseen, such as new medical technologies that would make our product obsolete. Any failure to implement our business strategy may adversely affect our business, results of operations, and financial condition. Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel. We are dependent upon the continued services of key members of our senior management and a number of key advisors and personnel. The loss of members of our senior management team, key advisors or personnel, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, results of operations, and financial condition. We do not maintain " key person " insurance for any of our executives or employees. In addition, several of the members of our executive management team are not subject to non- competition agreements that restrict their ability to compete with us. Accordingly, the adverse effect resulting from the loss of certain executives could be compounded by our inability to prevent them from competing with us. ~~26Various~~ -- **Various** factors outside our direct control may adversely affect manufacturing and distribution of our product. The manufacture and distribution of our product is challenging. Changes that our contract manufacturers may make outside the purview of our direct control can have an impact on our processes, quality of our product, and the successful delivery of products to our customers. Mistakes and mishandling are not uncommon and can affect supply and delivery. Some of these risks include: ● failure to manufacture in compliance with the required regulatory standards; ● transportation risk; ● the cost and availability of components and supplies required by our contract manufacturers to manufacture our products; ● delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products; ● natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment, or other forms of disruption to business operations affecting our manufacturers or their suppliers; and ● latent defects that may become apparent after products have been released and that may result in a recall of such products. If any of these risks were to materialize, our ability to provide our product to customers on a timely basis would be adversely impacted. We are dependent on a limited number of contract manufacturers, some of them single- source and some of them in single locations, for our product, and the loss of any of these contract manufacturers, or their inability to provide us with an adequate supply of products in a timely and cost- effective manner, could materially adversely affect our business. We rely on contract manufacturers to supply our product. For us to be successful, our contract manufacturers must be able to provide us with product in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable prices, and on a timely basis. We have a limited history with our current contract manufacturers and do not have long- term supply contracts with them. We are in the process of identifying and evaluating new contract manufacturers for our product. The inability to find the required contract manufacturers or the time required to switch contract manufacturers could adversely affect sales. In addition, our anticipated growth could strain the ability of our contract manufacturers to deliver an increasingly large supply of product. Contract manufacturers often experience difficulties in scaling up production, including financial issues, or problems with production yields and quality control and assurance. We use a small number of contract manufacturers for our instruments. Our dependence on such a limited number of contract manufacturers exposes us to risks, including, among other things: ● contract manufacturers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the

safety or effectiveness of our product or cause delays in shipments of our product; ● some of our contract manufacturers have long lead times of 12 to 16 weeks and we may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our contract manufacturers may have excess or inadequate inventory of materials and components; ● our contract manufacturers may be subject to price fluctuations due to a lack of long- term supply arrangements for key components; ● our contract manufacturers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our product; ● we may experience delays in delivery by our contract manufacturers due to changes in demand from us or their other customers; ● fluctuations in demand for products that our contract manufacturers manufacture for others may affect their ability or willingness to deliver our product to us in a timely manner; ● our contract manufacturers may wish to discontinue supplying products or services to us for risk management reasons; ● we may not be able to find new or alternative contract manufacturers in a timely manner if our current contract manufacturers stop producing products; and ● our contract manufacturers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfil our orders and meet our requirements. ~~27~~ If any one or more of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our product. If we are unable to satisfy commercial demand for our product in a timely manner, our ability to generate revenue would be impaired, market acceptance of our product could be adversely affected, and customers may instead purchase or use our competitors' products. Additionally, we could be forced to seek alternative sources of supply. Because of the nature of our internal quality control requirements, regulatory requirements, and the custom and proprietary nature of our product, we may not be able to quickly engage additional or replacement contract manufacturers for our product and accessories. We may also be required to assess any potential new contract manufacturer' s compliance with all applicable regulations and guidelines, which could further impede our ability to obtain our product in a timely manner. As a result, we could incur increased product costs, experience delays in deliveries of our product, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Failure of any of our contract manufacturers to meet our product demand level would limit our ability to meet our sales commitments to our customers and could have a material adverse effect on our business. We may also have difficulty obtaining similar product from other contract manufacturers that are acceptable to the FDA and the failure of our contract manufacturers to comply with strictly enforced regulatory requirements could expose us to delays in obtaining clearances or approvals, regulatory action including warning letters, product recalls, termination of distribution, product seizures, civil, administrative, or criminal penalties. We could incur delays while we locate and engage qualified alternative contract manufacturers, and we may be unable to engage alternative contract manufacturers on favorable terms or at all. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate sales. In addition, we expect that most of our contract manufacturers will operate at a facility in a single location and substantially all their inventory of component supplies and finished goods will be held at these locations. We, and our contract manufacturers, will take precautions to safeguard facilities, including acquiring insurance, adopting health and safety protocols, and utilizing off- site storage of computer data. However, vandalism, terrorism, or a natural or other disaster, such as an earthquake, fire, or flood, could damage or destroy equipment or component supplies or finished product, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our contract manufacturers' facilities could harm our business, financial condition, and operating results. As our sales grow, our contract manufacturers may encounter problems or delays in the manufacturing of our product or fail to meet certain regulatory requirements which could result in an adverse effect on our business and financial results. To become profitable, our contract manufactures must manufacture our product in adequate quantities in compliance with regulatory requirements and at an acceptable cost. Increasing their capacity to manufacture and inspect our product may require them to improve internal efficiencies or require us to re- design or change the specifications of our product. Our contract manufacturers may encounter several difficulties in increasing this capacity, including: ● managing production yields; ● maintaining quality control and assurance; ● providing component and service availability; ● maintaining adequate control policies and procedures; ● hiring and retaining qualified personnel; and ● complying with state, federal, and foreign regulations. ~~28If~~ **If** we are unable to satisfy commercial demand for ~~The CATAMARAN~~ **the Catamaran** System due to our contract manufacturer' s inability to manufacture and inspect our product, our ability to generate revenue would be impaired, market acceptance of our product could be adversely affected and customers may instead purchase or use our competitors' products. The size and future growth in the market for the SI- Joint fixation market have not been established based on market reports and our estimates are based on our own review and analysis of public information and may be smaller than we estimate, possibly materially. In addition, our estimates of cost savings to the economy and healthcare system as a result of ~~The CATAMARAN~~ **the Catamaran** System procedure are based on our internal estimates and market research and could also be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market or cost savings, our sales growth may be adversely affected. We are not aware of an independent third- party study that reliably reports the potential market size for the SI- Joint fixation market. Therefore, our estimates of the size and future growth in the market for ~~The CATAMARAN~~ **the Catamaran** System product, including cost savings to the economy overall, including patients and employers, and to the healthcare system and the number of people currently suffering from lower back pain who may benefit from and be amenable to our procedure, is based on a number of internal and third- party studies, surveys, reports, and estimates. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for our product and procedures and health cost savings, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. For example, we have consulted with our clinical advisors and utilized public information as the basis for our market projections. Additionally, the surveys we have conducted are based on a small number of respondents and are not statistically significant and may have other limitations. The actual incidence of lower back pain, and the actual demand for our product or competitive

products, could differ materially from our projections if our assumptions and estimates are incorrect. As a result, our estimates of the size and future growth in the market for our product may prove to be incorrect. In addition, actual health cost savings to the healthcare system as a result of ~~The CATAMARAN~~ **the Catamaran** System procedure may materially differ from those presented in this report. If the actual number of people with lower back pain who would benefit from ~~The CATAMARAN~~ **the Catamaran** System and the size and future growth in the market and related costs savings to the healthcare system is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business. In the future our product may become obsolete, which would negatively affect operations and financial condition. The medical device industry is characterized by rapid and significant change. There can be no assurance that other companies will not succeed in developing or marketing devices, and products that are more effective than ~~The CATAMARAN~~ **the Catamaran** System or that would render ~~The CATAMARAN~~ **the Catamaran** System obsolete or non- competitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our product. Accordingly, our success will depend in part on our ability to respond quickly to medical and changes through the development and introduction of new products. Product development involves a high degree of risk and there can be no assurance that our new product development efforts will result in any commercially successful products. If we experience significant disruptions in our information technology systems, our business, results of operations, and financial condition could be adversely affected. The efficient operation of our business depends on our information technology systems. We will rely on our information technology systems to effectively manage: ● sales and marketing, accounting, and financial functions; ● inventory management; ● engineering and product development tasks; and ● our research and development data. Our information technology systems are vulnerable to damage or interruption from: ● earthquakes, fires, floods, and other natural disasters; ● terrorist attacks and attacks by computer viruses or hackers; ● power losses; and ● computer systems, or Internet, telecommunications, or data network failures. ~~29~~ The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our entire operation and could result in decreased sales, increased overhead costs, excess inventory and product shortages, and legal liability issues, all of which could have a material adverse effect on our reputation, business, results of operations, and financial condition. We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us. From time to time, we expect to consider opportunities to acquire or make investments in other technologies, products, and businesses that may enhance our capabilities, complement our current product, or expand the breadth of our markets or customer base. Potential and completed acquisitions and strategic investments involve numerous risks, including: ● problems assimilating the purchased technologies, products, or business operations; ● issues maintaining uniform standards, procedures, controls, and policies; ● unanticipated costs and liabilities associated with acquisitions; ● diversion of management' s attention from our core business; ● adverse effects on existing business relationships with suppliers and customers; ● risks associated with entering new markets in which we have limited or no experience; ● potential loss of key employees of acquired businesses; and ● increased legal and accounting compliance costs. We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to identify acquisitions, we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired business, product, or technology into our business or retain any key personnel, suppliers, or distributors. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete, and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time consuming and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to successfully integrate any acquired businesses, products, or technologies effectively, our business, results of operations, and financial condition will be materially adversely affected. We may enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances, or partnerships with third- parties that may not result in the development of commercially viable products or the generation of significant future revenue. In the ordinary course of our business, we may enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances, partnerships, or other arrangements to develop products and to pursue new markets. We have not entered into any collaboration arrangements to date. Proposing, negotiating, and implementing collaborations, in- licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. 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. These collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products. Additionally, we may not be able to exercise sole decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. ~~30Disputes~~ -- **Disputes** between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in

such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in- bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects. We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks. Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we will collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. We have also outsourced significant elements of our information technology infrastructure; as a result, we manage independent vendor relationships with third parties who are responsible for maintaining significant elements of our information technology systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third- party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors. These systems are also vulnerable to attacks by malicious third parties and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties. Maintaining the secrecy of confidential, proprietary and / or trade secret information is important to our competitive business position. While we have taken steps to protect such information and have invested in systems and infrastructures to do so, there can be no guarantee that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination or misuse of critical or sensitive information. **The increasing sophistication and frequency of cybersecurity threats, including targeted data breaches, ransomware attacks designed to encrypt our data for ransom and other malicious cyber activities, pose a significant risk to the integrity and confidentiality of our data systems.** A breach our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and / or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations and / or cash flow. Geopolitical conditions, including trade disputes and direct or indirect acts of war or terrorism, could have an adverse effect on our operations and financial results. ~~Recently~~ **Our operations could be disrupted by geopolitical conditions, political and social instability, acts of war, terrorist activity or other similar events. In February 2022** , Russia initiated significant military action against Ukraine. In response, the U. S. and certain other countries imposed significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations, and the U. S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U. S. and other countries in respect thereof as well as any counter measures or retaliatory actions by Russia or Belarus in response, including, for example, potential cyberattacks or the disruption of energy exports, is likely to cause regional instability, geopolitical shifts, and could materially adversely affect **global trade, currency exchange rates,** regional economies and the global economy. **In addition, the ongoing conflicts in the Middle East may further impact global economic conditions and market sentiments. This, in turn, could adversely affect the trading price of our shares of common stock and investor interest in us.** The ~~situation~~ **outcome of the Russia- Ukraine war and conflicts in the Middle East** ~~remains~~ **remain** uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, **and results of operations. Inflation may adversely affect our operations and financial results. In periods of rising inflation, the cost of raw materials, components and labor essential for manufacturing the Catamaran System may increase and as a consequence, our overall profit margin may be adversely affected. In addition, inflation may result in limitations on healthcare spending, specifically for procedures that are deemed elective or non- critical, which may include treatments utilizing the Catamaran System. A decrease in demand for these procedures may significantly impact our financial condition** and results of operations. The failure of Silicon Valley Bank could cause us to lose our deposits in excess of the federally insured bank deposit limitation. On March 10, 2023, the Federal Deposit Insurance Corporation (the " FDIC ") took control of Silicon Valley Bank (" SVB ") and created the National Bank of Santa Clara to hold the deposits of SVB after SVB was unable to continue their operations. SVB' s deposits are insured by the FDIC in amount up to $ 250, 000 for any depositor and any deposit in excess of this insured amount could be lost. As of March 10, 2023, we had approximately $ 585, 000 on deposit with SVB, of which approximately $ 335, 000 will not be insured by the FDIC (the " Uninsured Amount "). We expect to have access to the insured portion of our SVB deposit in the coming days, but do not know when, if ever, we will have access to the Uninsured Amount. The loss of all or a significant portion of the Uninsured Amount would not have an adverse effect on our ability to pay our operational expenses or make other payments, but may require the Company to move our

accounts to another bank which could cause a temporary delay in making payments to our vendors and employees and cause other operational inconveniences. ~~31~~ Risks Related to Our Legal and Regulatory Environment We and our contract manufacturers are subject to extensive governmental regulation both in the United States and abroad, and failure to comply with applicable requirements could cause our business to suffer. The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The FDA and other U. S. and foreign governmental agencies regulate, among other things, with respect to medical devices: ● design, development, and manufacturing; ● testing, labeling, content, and language of instructions for use and storage; ● clinical trials; ● product safety; ● marketing, sales, and distribution; ● premarket clearance and approval; ● conformity assessment **procedures; ● record keeping** procedures; ● advertising and promotion; ● compliance with good manufacturing practices requirements; ● recalls and field safety corrective actions; ● post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; ● post- market approval studies; and ● product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, difficulties achieving new product clearances, higher than anticipated costs or lower than anticipated sales. Before we can market or sell a new regulated product or make a significant modification to an existing product in the United States, with very limited exception, we must obtain either clearance under Section 510 (k) of the FDCA for Class II devices or approval of a premarket approval application from the FDA for a Class III device. In the 510 (k) clearance process, the FDA must determine that a proposed device is " substantially equivalent " to a device legally on the market, known as a " predicate " device, with respect to intended use, technology, and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life-supporting, or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510 (k) may require a new 510 (k). Both the 510 (k) and PMA processes can be expensive and lengthy and require the payment of significant fees, unless exempt. The FDA' s 510 (k) clearance process usually takes from three to 12 months but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510 (k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining domestic and international regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In the United States, all of the components to ~~The CATAMARAN~~ **the Catamaran** System have either received premarket clearance under Section 510 (k) of the FDCA or are exempt from premarket review. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy, and uncertain PMA process. Although we do not currently market any devices under PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product, we currently market is subject to an exemption from premarket review, the FDA may require us to submit a 510 (k) or PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain the 510 (k) clearances with respect to those products. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: ● we may not be able to demonstrate to the FDA' s satisfaction that our product is safe and effective for their intended users; ● the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and ● the manufacturing process or facilities we use may not meet applicable requirements. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay clearance or approval of our product under development or impact our ability to modify our currently approved or cleared product on a timely basis. Any delay in, or failure to receive or maintain, clearance or approval for our product under development could prevent us from generating revenue from these products or achieving profitability. In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post- market surveillance on our product. These studies can be very expensive and time consuming to conduct. Failure to comply with those studies in a timely manner could result in the revocation of the 510 (k) clearance for a product that is subject to such surveillance and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States. Additionally, as part of the conformity assessment process, medical device manufacturers must carry out a clinical evaluation of their medical devices to verify that they comply with the relevant Essential Requirements covering safety and performance. A clinical evaluation includes an assessment of whether a medical device' s performance is in accordance with its intended use and that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions / warnings) and the suitability of related Instructions for Use. This assessment must be based on clinical data, which can be obtained from (i) clinical studies conducted on the devices being assessed; (ii) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated; or (iii) both clinical studies and scientific literature. The FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some clinicians from using our product and adversely affect our reputation and the perceived safety and effectiveness of our product. Failure to comply with applicable regulations could jeopardize our ability to sell our product and

result in enforcement actions such as: ● warning letters; ● fines; ● injunctions; ● civil penalties; ● termination of distribution; ● recalls or seizures of products; ● delays in the introduction of products into the market; ● total or partial suspension of production; ● facility closures; ● refusal of the FDA other regulators to grant future clearances or approvals; or ● in the most serious cases, criminal penalties. Adverse action by an applicable regulatory agency the FDA could result in inability to produce our product in a cost- effective and timely manner, or at all, decreased sales, higher prices, lower margins, additional unplanned costs or actions, damage to our reputation, and could have material adverse effect on our reputation, business, results of operations, and financial condition. We and our independent sales representatives must comply with U. S. federal and state fraud and abuse laws, including those relating to physician kickbacks and false claims for reimbursement. Healthcare providers, distributors, physicians, and third- party payors play a primary role in the distribution, recommendation, ordering, and purchasing of any implant or other medical device for which we have or obtain marketing clearance or approval. Through our arrangements with customers and third- party payors, we are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, or independent sales representatives may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and / or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete, and accurate reporting of financial information or data, other commercial or regulatory laws or requirements, and equivalent foreign rules. We plan to implement a compliance program, code of conduct, and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we plan to take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and government authorities may conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance despite our good faith efforts to comply. There are numerous U. S. federal and state laws pertaining to healthcare fraud and abuse, including anti- kickback and false claims laws. Our relationships with clinicians, other healthcare professionals, and hospitals are subject to scrutiny under these laws. Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include: ● the federal Anti- Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs; ● the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds; knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease, or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. There are also criminal penalties for making or presenting a false or fictitious or fraudulent claim to the federal government; ● the federal Health Insurance Portability and Accountability Act of 1996, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program including private third- party payors, or knowingly and willfully falsifying, concealing, or covering up a material fact or making a materially false, fictitious, or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services; ● the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services information related to payments or other " transfers of value " made to physicians and teaching hospitals, and requires applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other " transfers of value " to such physician owners; and ● analogous state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. If we or our employees are found to have violated any of the above laws we may be subjected to administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties and damages, and damage to our reputation. Additional information about these laws is provided in " Business — Regulation. " We have entered into consulting agreements with clinicians who are also customers. We anticipate entering into additional agreements with clinicians who use our product as we continue to commercialize our product. The primary mission of these clinician advisors is research and development and clinician education. Medical device technology development requires thoughtful clinician input from experienced healthcare professionals. Medical device clinician education requires experienced faculty for didactic and anatomic lab activities in a peer- to- peer setting. We believe these engagements will allow us to successfully meet the expectations of the physician community. In addition, a small number of clinicians (which are or may become customers) own less than 1. 0 % of our stock, or were granted stock options which they either purchased in an arm' s length transaction on terms identical to those offered to others or

received from us as fair market value consideration for consulting services performed. While all of these transactions were structured with the intention of complying with all applicable laws, including the federal Anti- Kickback Statute, state anti-kickback laws and other applicable laws, to the extent applicable, it is possible that regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to significant penalties. We would be materially and adversely affected if regulatory agencies interpret our financial relationships with clinicians who order our product to be in violation of applicable laws and we were unable to comply with such laws, which could subject us to, among other things, monetary penalties for non- compliance, the cost of which could be substantial. In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved, or " off- label " uses of their products. Pursuant to FDA regulations, we can only market our product for cleared or approved uses. Although clinicians are permitted to use medical devices for indications other than those cleared or approved by the FDA, we are prohibited from promoting products for " off- label " uses. We market our product and provide promotional materials and training programs to clinicians regarding the use of our product. If it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, criminal penalty, and damage to our reputation. Federal and state authorities also pursue actions for false claims based upon improper billing and coding advice or recommendations, as well as decisions related to the medical necessity of procedures, including the site- of- service where procedures are performed. Actions under the federal False Claims Act may also be brought by whistleblowers under its qui tam provisions. To enforce compliance with the federal laws, the U. S. Department of Justice has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management' s attention from the business. Additionally, if a healthcare company settles an investigation with the Department of Justice or other law enforcement agencies, it may need to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business. The scope and enforcement of these laws is uncertain and subject to rapid change. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and / or reporting requirements in multiple jurisdictions increase the possibility that we may run afoul of one or more of the requirements or that federal or state regulatory authorities might challenge our current or future activities under these laws. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive. Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business. In the ordinary course of our business, we plan to collect and store sensitive data, including legally protected personally identifiable information. We may collect this kind of information during the course of future clinical trials and for possible post- marketing safety vigilance, helping enable clinicians and their patients to pursue claims for reimbursement for procedures using ~~The CATAMARAN~~ **the Catamaran** System and servicing potential warranty claims. There are a number of state, federal, and international laws protecting the privacy and security of health information and personal data. These data protection and privacy- related laws and regulations are evolving and may result in ever- increasing regulatory and public scrutiny of companies' data practices and escalating levels of enforcement and sanctions. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes certain requirements regarding the privacy, security, use, and disclosure of an individual' s protected health information, or PHI, by certain health care providers, health care clearinghouses, and health insurance plans, collectively referred to as " covered entities, " and their " business associates, " or subcontractors who provide services to covered entities that involve the creation, use, maintenance, or disclosure of PHI. ARRA included significant increases in the penalties for improper use or disclosure of an individual' s PHI under HIPAA and extended enforcement authority to state attorneys general. The amendments also created notification requirements applicable to covered entities and business associates in certain cases when PHI in their control has been inappropriately accessed or disclosed. In the case of a breach of unsecured PHI, covered entities may be required to provide notification to individuals affected by the breach, federal regulators, and, in some cases, local and national media. In addition to HIPAA, most states have laws requiring notification of affected individuals and state regulators in the event of a breach of " personal information, " which is a broader class of information than the PHI protected by HIPAA. Certain states also have data privacy requirements applicable to individually identifiable health information. Privacy laws in different states may contain different requirements, and such laws may not be pre- empted by HIPAA, which could complicate our efforts to comply . ~~18In~~ **In** addition,even when HIPAA does not apply,according to the FTC,failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the FTCA,15 U.S.C § 45 (a).The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds,the size and complexity of its business,and the cost of available tools to improve security and reduce vulnerabilities.Medical data is considered sensitive data that merits stronger safeguards.The FTC' s guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule . Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end- customers, and other affected individuals, and the imposition of integrity obligations and agency oversight, damage to our reputation, and loss of goodwill, any of which could harm on our operations, financial performance, and business. Evolving and changing definitions of personal data and personal information, within the United States, and

elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our product, or if we expand into new regions and are required to comply with new requirements, we may need to expend resources in order to change our business operations, data practices, or the manner in which our product operates. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our product. Even if our product is approved by regulatory authorities if our contract manufacturers fail to comply with ongoing FDA, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market. Any product for which we obtain regulatory clearance or approval, and the manufacturing processes, reporting requirements, post- approval clinical data, and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic bodies. In particular, we and our contract manufacturers are required to comply with FDA' s Quality System Regulations (" QSR ") for the manufacture of our product and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain regulatory clearance or approval. The failure by us or one of our contract manufacturers to comply with applicable statutes and regulations, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions: ● untitled letters, warning letters, fines, injunctions, consent, and civil penalties; ● unanticipated expenditures to address or defend such actions; ● **customer notifications for repair, replacement, refunds; ●** recall, detention, or seizure of our product **; ● operating restrictions or partial suspension or total shutdown of production** ; ● refusing or delaying our requests for 510 (k) clearance or premarket approval and conformity assessments of new products or modified products; ● limitations on the intended uses for which the product may be marketed **; ● operating restrictions** ; ● withdrawing 510 (k) clearances or PMA approvals that have already been granted; or **● criminal prosecution.** In addition, we may be required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our product, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our product. Later discovery of previously unknown problems with our product, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace, or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation, or withdrawal of regulatory approvals product seizures, injunctions, or the imposition of civil, administrative, or criminal penalties which would adversely affect our business, operating results, and prospects. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional 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 or fraudulent claims for payment of government funds. If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our product on a timely basis and in the required quantities, if at all. The FDA has not yet inspected our facility, but we expect an inspection in the future. Our employees, independent contractors, consultants, contract manufacturers, and our independent sales representatives may engage in misconduct or other improper activities, relating to regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, contract manufacturers, and our independent sales representatives may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We plan to implement a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, disgorgement of profits, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We may be subject to enforcement action, including fines, penalties or injunctions, if we are determined to be engaging in the off- label promotion of our product. Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off- label use. Physicians may use our product off- label, as the FDA does not restrict or regulate a physician' s choice of treatment within the practice of medicine. In the United States, the full indication for ~~The CATAMARAN~~ **the Catamaran** System is: " The Tenon Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) is intended for sacroiliac joint fusion for conditions

including sacroiliac joint disruptions and degenerative sacroiliitis. ” Contraindications are patients with the following conditions: skeletally immature spines; deformities; severe osteoporosis; morbid obesity, tumor resection and active infection at treatment site. We believe that the specific surgical procedures for which our product are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, 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, require us to stop promoting our product for those specific procedures until we obtain FDA clearance or approval for them, or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines, and criminal penalties. 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 or fraudulent claims for payment of government fund. In that event, our reputation could be damaged, and adoption of the product would be impaired. Although our policy is to refrain from statements that could be considered off- label promotion of our product, the FDA or another regulatory agency could disagree and conclude that we have engaged in off- label promotion. In addition, the off- label use of our product 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, result in substantial damage awards against us and harm our reputation. We are required to report certain malfunctions, deaths, and serious injuries associated with our product, which can result in voluntary corrective actions or agency enforcement actions. Further, under the FDA’ s medical device reporting regulations, we are required to report to the FDA any information that our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our product or repeated product malfunctions may result in a voluntary or involuntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit could divert managerial and financial resources, impair our ability to manufacture our product in a cost- effective and timely manner, and have an adverse effect on our reputation, results of operations, and financial condition. Any adverse event involving our product in the United States could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. A recall of our product, either voluntarily or at the direction of the FDA or the discovery of serious safety issues or malfunctions with our product, can result in voluntary corrective actions or agency enforcement actions, which could have a significant adverse impact on us. The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is an unreasonable risk of substantial public harm. In addition, foreign governmental bodies have the authority to require the recall of our product in the event of material deficiencies or defects in design or manufacture. A government- mandated or voluntary recall by us or one of the independent sales representatives could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our product would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to produce our product in a cost- effective and timely manner in order to meet our customers’ demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our product in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could 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 action for failing to report the recalls when they were conducted. Modifications to our product may require new 510 (k) clearances or premarket approvals may require us to cease marketing or recall the product until clearances Any modification to a 510 (k)- cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510 (k) clearance or, possibly, a PMA. The FDA requires every manufacturer make and document this determination in the first instance. A manufacturer may determine that a modification could not significantly affect safety or effectiveness and does not represent a major change in its intended use, so that no new 510 (k) clearance is necessary. FDA may review any manufacturer’ s decision and may not agree with our decisions regarding whether new clearances or approvals are necessary. The FDA may also on its own initiative determine that a new clearance or approval is required. We have modified our product and have determined based on our review of the applicable FDA guidance that a new 510 (k) clearances or PMAs is not required. If the FDA disagrees with our determination and requires us to submit new 510 (k) clearances or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant enforcement action, regulatory fines, or penalties. If a manufacturer determines that a modification to an FDA- cleared device could significantly affect its safety or effectiveness or

would constitute a major change in its intended use, then the manufacturer must file for a new 510 (k) clearance or possibly a premarket approval application. Where we determine that modifications to our product require a new 510 (k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. FDA' s ongoing review of the 510 (k) programs may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510 (k) for a modification to a previously cleared product must be submitted or applying more onerous review criteria to such submissions. Clinical trials necessary to support a 510 (k) or reimbursement may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials could affect third party reimbursement as many of the payors want to see peer reviewed articles to maintain coverage and lack of changes in reimbursement could materially slow down our commercial efforts and affect our revenue projections. The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects. If our clinical trials are completed as planned, we cannot be certain that their results will support our product marketing claims or third party reimbursors will agree with our conclusions regarding them. The clinical trial process may fail to demonstrate efficacy and cost effectiveness of our product and may hinder the adoption of our product or ability to obtain payor coverage. 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. We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses. Our business exposes us to potential product liability claims that are inherent in the testing, design, manufacture, and sale of medical devices for SI- Joint surgery procedures. SI- Joint surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis, and even death. In addition, if longer- term patient results and experience indicates that our product or any component of such product cause tissue damage, motor impairment, or other adverse effects, we could be subject to significant liability. Clinicians may misuse or ineffectively use our product, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects, or inadequate disclosure of product- related risks or product- related information resulted in an unsafe condition or injury to patients. Product liability lawsuits and claims, safety alerts, or product recalls, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation, our ability to attract and retain customers and our results of operations or financial condition. Although we maintain third- party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies or cause us to record a self- insured loss. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial retentions or deductibles that we are responsible for. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, results of operations, and financial condition. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance rates. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all. We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities. Our business and facility and those of our contract manufacturer 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. 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. U. S. tax legislation may materially affect our financial condition, results of operations and cash flows. The Tax Cuts and Jobs Act (the " Tax Act ") has significantly changed the U. S. federal income taxation of U. S. businesses, including by reducing the U. S. corporate income tax rate, limiting interest deductions, permitting immediate expensing of certain capital expenditures, modifying or repealing many business deductions and credits. The Coronavirus Aid, Relief, and Economic Security Act (the " CARES Act ") modifies certain provisions of the Tax Act, including increasing the amount of interest expense that may be deducted. The Tax Act as modified by the CARES Act is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U. S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. Our analysis and interpretation of this legislation is preliminary and ongoing and there may be material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us, other changes may be beneficial. We continue to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and its potential effect on an investment in our common stock. Risks Related to Our Intellectual Property Our ability to protect our intellectual property and proprietary technology is uncertain. We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and non- disclosure agreements and other methods, to protect our proprietary technologies and know- how. As of March ~~10~~ **29** , ~~2023~~ **2024** , we owned eight issued patents (four domestic and four foreign), eighteen pending patent applications (sixteen domestic and two foreign), thirteen registered trademarks (seven domestic and six foreign) and twelve pending domestic trademark applications. We have applied for patent protection relating to certain existing and proposed products and processes. While we generally apply for patents in those countries where we intend to make, have made, use, or sell patented products, we may not accurately predict all the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so later. Furthermore, we cannot assure you that any of our patent applications will be

approved. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested, or circumvented by our competitors or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U. S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available. Since most of our issued patents are for the United States only, we lack a corresponding scope of patent protection in other countries. In countries where we do not have significant patent protection, we may not be able to stop a competitor from marketing products in such countries that are the same as or similar to our product. We plan to rely on our trademarks, trade names and brand names to distinguish our product from the products of our competitors and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks. We also rely on trade secrets, know- how, and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality and intellectual property assignment agreements with parties that develop intellectual property for us and / or have access to it, such as our officers, employees, consultants, contract manufacturers and advisors. However, in the event of unauthorized use or disclosure or other breaches of such agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. If any of our trade secrets, know- how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business, financial condition, and results of operations could be materially adversely affected. In the future, we may enter into licensing agreements to maintain our competitive position. If we enter into in- bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain, and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek damages or to terminate our license, which could adversely affect our competitive business position and harm our business prospects. If a competitor infringes upon one of our patents, trademarks, or other intellectual property rights, enforcing those patents, trademarks, and other rights may be difficult and time consuming. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management' s attention from managing our business. Moreover, we may not have sufficient resources to defend our patents or trademarks against challenges or to enforce our intellectual property rights. In addition, if third parties infringe any intellectual property that is not material to the products that we make, have made, use, or sell, it may be impractical for us to enforce this intellectual property against those third parties. We may be subject to damages resulting from claims that we, our employees, or independent distributors along with their independent sales representatives have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. Some independent distributors and their independent sales representatives sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees or independent sales personnel have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement. Even if we are successful in defending against these claims, litigation could result in substantial costs, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There can be no assurance that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations, and financial condition. The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management' s time and efforts, require us to pay damages, and / or prevent us from developing or marketing our existing or future products. Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make and sell our product. We have conducted a limited review of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the

complexities of the technology involved, and the uncertainty of litigation increase the risk of business assets and management' s attention being diverted to patent litigation. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. Further, as the number of participants in the medical device industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, including treble, or triple, damages if an infringement is found to be willful, and / or royalties and could be prevented from selling our product unless we obtain a license or are able to redesign our product to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our product in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our product or technologies, we may have to withdraw our existing product from the market or may be unable to commercialize one or more of our future products, all of which could have a material adverse effect on our business, results of operations, and financial condition. If passed into law, patent reform legislation currently pending in the U. S. Congress could significantly change the risks associated with bringing or defending a patent infringement lawsuit. For example, fee shifting legislation could require a non- prevailing party to pay the attorney fees of the prevailing party in some circumstances. Patent terms are limited, and we may not be able to effectively protect our product and business. Patents have a limited lifespan. In the U. S., the natural expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. In addition, upon issuance in the U. S., the patent term may be extended based on certain delays caused by the applicant (s) or the USPTO. Even if we obtain effective patent rights for all our current patent applications, we may not have sufficient patent terms or regulatory exclusivity to protect our product, and our business and results of operations would be adversely affected. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product. As is the case with other medical devices companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the medical devices industry involves both technological and legal complexity. Therefore, obtaining and enforcing patents is costly, time- consuming, and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U. S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U. S. These products may compete with our product and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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 and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants, contract manufacturers and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed. Third

parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Risks Related to the Ownership of our Common Stock The market for our common stock is new and may not develop to provide investors with adequate liquidity. We ~~only recently~~ conducted our initial public offering in April of 2022. Therefore, the market for our common stock is new, and we cannot assure you that an active trading market for our common stock will develop, or if it does develop, it may not be maintained. You may not be able to sell your common stock quickly or at the market price if trading in our securities is not active. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts provide coverage or if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, the price of our stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our stock could decrease, which might cause the price of our stock and trading volume to decline. The price of our common stock may be volatile, and you may be unable to resell your shares at or above the ~~offering~~ price **paid** . The trading price of our common stock may fluctuate substantially. The market price of our common stock may ~~be~~ **fluctuate** higher or lower ~~than the price investors paid in the offering~~ , depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include the following: ● actual or anticipated fluctuations in our financial condition and operating results; ● actual or anticipated changes in our growth rate relative to our competitors; ● commercial success and market acceptance of our product; ● success of our competitors in developing or commercializing products; ● ability to commercialize or obtain regulatory approvals for our product, or delays in commercializing or obtaining regulatory approvals; ● strategic transactions undertaken by us; ● additions or departures of key personnel; ● product liability claims; ● prevailing economic conditions; ● disputes concerning our intellectual property or other proprietary rights; ● FDA or other U. S. or foreign regulatory actions affecting us or the healthcare industry; ● healthcare reform measures in the United States; ● sales of our common stock by our officers, directors or significant stockholders; ● future sales or issuances of equity or debt securities by us; ● business disruptions caused by earthquakes, fires or other natural disasters; ● the exercise and sale of any outstanding warrants or options; ● issuance of new or changed securities analysts' reports or recommendations regarding us; ~~and~~ ● ~~Covid- 19 restrictions~~ **changes in our capital structure, such as future issuances of debt or equity securities; ● short sales, hedging and other derivative transactions involving our capital stock; and ● general economic and geopolitical conditions, including the current or anticipated impact of military conflict and related sanctions imposed** on ~~elective surgeries~~ **Russia by the United States and other countries due to Russia' s recent invasion of Ukraine** . In addition, if the market for medical device or healthcare stocks or the stock market, in general, experience a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations, or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, following periods of volatility in the market price of a company' s securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management' s attention and resources from our business. This could have a material adverse effect on our business, results of operations, and financial condition. The price and volume of our common stock may rapidly fluctuate or may decline regardless of our operating performance, resulting in substantial losses for investors. The trading price of our common stock may be subject to instances of extreme stock price run- ups followed by rapid price declines and stock price volatility unrelated to both our actual and expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our stock. Further, the trading price of our common stock could be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume, actual or anticipated fluctuations in our results of operations; the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections; failure of securities analysts to initiate or maintain coverage of our Company, changes in financial estimates or ratings by any securities analysts who follow our Company or our failure to meet these estimates or the expectations of investors; announcements by us or our competitors of significant innovations, acquisitions, strategic partnerships, joint ventures, operating results or capital commitments; changes in operating performance and stock market valuations of other companies in our industry; price and volume fluctuations in the overall stock market, including as a result of trends in the economy as a whole; changes in our Board or management; sales of large blocks of our Common Stock, including sales by our executive officers, directors and significant stockholders; lawsuits threatened or filed against us; changes in laws or regulations applicable to our business; the expiration of lock- up agreements; changes in our capital structure, such as future issuances of debt or equity securities; short sales, hedging and other derivative transactions involving our capital stock; general economic and geopolitical conditions, including the current or anticipated impact of military conflict and related sanctions imposed on Russia by the United States and other countries due to Russia' s recent invasion of Ukraine; and the other factors described in this section of

the report captioned " Risk Factors. " Sales of substantial amounts of our common stock in the public markets, or the perception that sales might occur, could reduce the price of our common stock and may dilute our current stockholders voting power and their ownership interest in us. Sales of a substantial number of shares of our common stock in the public or the perception that these sales could occur, could adversely affect the market price of our common stock, and may make it more difficult for holders of our common stock to sell their common stock at a time and price that you deem appropriate and affect our ability to raise capital through the sale of equity securities. We may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline. We may be subject to securities litigation, which is expensive and could divert our management' s attention. The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns. We may not be able to satisfy listing requirements of Nasdaq to maintain a listing of our common stock. We must meet certain financial and liquidity criteria to maintain the listing of our common stock on **the** Nasdaq **Stock Market LLC (" Nasdaq ")** . If we violate the maintenance requirements for continued listing of our common stock, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital **. On January 4, 2024, we received a written notice (the " Notice ") from Nasdaq dated January 4, 2024, indicating that, as a result of Frank Fischer' s resignation from the Board, audit committee of the Board (the " Audit Committee ") and compensation committee of the Board (the " Compensation Committee "), effective November 30, 2023, that the Company was not currently in compliance with Nasdaq Listing Rule 5605, which requires that (i) a majority of the Board be comprised of independent directors, (ii) the Audit Committee is comprised of at least three independent directors and (iii) the Compensation Committee is comprised of at least two independent directors. Kristine Jacques was appointed to the Board on March 25, 2024 and as a result, as of March 25, 2024, the Company partly complied with Nasdaq Listing Rule 5605, specifically the requirement that a majority of the Board be comprised of independent directors. The Audit Committee, however, currently is comprised of only two independent directors and the Compensation Committee is only comprised of one independent director. In accordance with Nasdaq Listing Rule 5605 (b) (1) (A), the Company has a " cure period " of until the earlier of the Company' s next annual shareholders' meeting or November 30, 2024, or if the next annual shareholders' meeting is held before May 28, 2024, then the Company must evidence compliance no later than May 28, 2024. The Company intends to elect one or more independent directors to serve as a member of the Audit Committee and the Compensation Committee during this cure period. The Notice has no immediate effect on v listing or trading of the Company' s common stock on The Nasdaq Capital Market** . Our failure to maintain effective internal controls over financial reporting could have an adverse impact on us. We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely impact our public disclosures regarding our business, financial condition, or results of operations. In addition, management' s assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting, disclosure of management' s assessment of our internal controls over financial reporting or disclosure of our public accounting firm' s attestation to or report on management' s assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no system of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision- making can be faulty and that breakdowns can occur because of simple error or mistake. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of inherent limitations in a cost- effective control system, misstatements due to error or fraud may occur and may not be detected. At present, management has identified a material weakness due to lack of segregation of duties. The lack of segregation of duties existed as a result of the Company having no employees until June 2021. Management has taken initial steps to remedy this weakness by hiring a Chief Financial Officer, a director of SEC reporting and compliance **,** and a senior accountant **,** and engaging a cost accounting consultant and external financial consultants, and plans to continue to add additional resources, technology and headcount as warranted by the growth of the Company. While we believe these efforts will improve our internal controls and address the underlying causes of the material weakness, such material weakness will not be remediated until our remediation plan has been fully implemented and we have concluded that our controls are operating effectively for a sufficient period of time. We cannot be certain that the steps we are taking will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or prevent future material weaknesses or control deficiencies from occurring. While we are working to

remediate the material weakness as timely and efficiently as possible, at this time we cannot provide an estimate of costs expected to be incurred in connection with the implementation of this remediation plan, nor can we provide an estimate of the time it will take to complete this remediation plan. Even if management does establish effective remedial measures, we cannot guarantee that those internal controls and disclosure controls that we put in place will prevent all possible errors, mistakes, or all fraud. Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which, as a public company, could materially harm our stock price. We will require significant financial resources to maintain our public reporting status. We cannot assure you we will be able to maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors including: ● faulty human judgment and simple errors, omissions or mistakes; ● fraudulent action of an individual or collusion of two or more people; ● inappropriate management override of procedures; and ● the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information. Our internal control over financial reporting will be a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company' s assets that could have a material effect on the financial statements. Despite these anticipated controls, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. Furthermore, smaller reporting companies like us face additional limitations. Smaller reporting companies employ fewer individuals and can find it difficult to employ resources for complicated transactions and effective risk management. Additionally, smaller reporting companies tend to utilize general accounting software packages that lack a rigorous set of software controls. If we fail to have effective controls and procedures for financial reporting in place, we could be unable to provide timely and accurate financial information and be subject to investigation by the SEC and civil or criminal sanctions. We must implement additional and expensive procedures and controls in order to grow our business and organization and to satisfy reporting requirements, which will increase our costs and require additional management resources. As a public company, we are required to comply with the Sarbanes- Oxley Act of 2002 (the " Sarbanes- Oxley Act ") and the related rules and regulations of the SEC, including the requirements that we maintain disclosure controls and procedures and adequate internal control over financial reporting. Compliance with the Sarbanes- Oxley Act and other SEC and national exchange requirements will increase our costs and require additional management resources. We have begun the process of upgrading our procedures and controls and will need to begin implementing additional procedures and controls as we grow our business and organization and to satisfy new reporting requirements. If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting, as required by Section 404 of the Sarbanes- Oxley Act or if we fail to establish and maintain internal control over financial reporting, our ability to produce timely, accurate and reliable periodic financial statements could be impaired. If we do not establish and maintain adequate internal control over financial reporting, investors could lose confidence in the accuracy of our periodic reports filed under the Exchange Act. Additionally, our ability to obtain additional financing could be impaired or a lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline. We are an " emerging growth company " under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act of 2012 (the " JOBS Act "), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not " emerging growth companies " including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, Section 107 of the JOBS Act also provides that an " emerging growth company " can take advantage of the extended transition period provided in Section 7 (a) (2) (B) of the Securities Act of 1933 (the " Securities Act ") for complying with new or revised accounting standards. In other words, an " emerging growth company " can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards. We will remain an " emerging growth company " until the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act, although we will lose that status sooner if our revenues exceed $ 1. 235 billion, if we issue more than $ 1 billion in non-convertible debt in a three year period, or we are deemed to be a large accelerated filer under applicable SEC rules. Our status as an " emerging growth company " under the JOBS Act may make it more difficult to raise capital as and when we need it. Because of the exemptions from various reporting requirements provided to us as an " emerging growth company " and because we will have an extended transition period for complying with new or revised financial accounting standards, we may be less attractive to investors, and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable

to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected. We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock. We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. We currently intend to retain any future earnings to support the development of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our board of directors after taking into account various factors, including, but not limited to, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. In addition, our ability to pay dividends on our common stock may be limited by Delaware state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize a return on their investment. Investors seeking cash dividends should not purchase our common stock. The elimination of personal liability against our directors and officers under Delaware law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses. Our amended and restated certificate of incorporation, as amended (" Certificate of Incorporation "), and our bylaws (" Bylaws ") eliminate the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Delaware law. Further, our Certificate of Incorporation allows for us to and our Bylaws provide that we are obligated to indemnify each of our directors or officers to the fullest extent authorized by Delaware law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit our stockholders. Our Certificate of Incorporation ~~will designate~~ **designates** the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Our Certificate of Incorporation specifies that, except for claims arising under federal securities laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company' s stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or Bylaws, or (d) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Certificate of Incorporation as described above. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. As such, stockholders of the Company seeking to bring a claim regarding the internal affairs of the Company may be subject to increased costs associated with litigating in Delaware as opposed to their home state or other forum, precluded from bringing such a claim in a forum they otherwise consider to be more favorable, and discouraged from bringing such claims as a result of the foregoing or other factors related to forum selection. Alternatively, if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition. We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees, and agents as it may limit any stockholder' s ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.