Risk Factors Comparison 2024-02-27 to 2023-03-02 Form: 10-K

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Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes and the section " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our common stock could decline, and our stockholders may lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Risks Related to Our Business and Our Industry We have incurred significant operating losses since inception, we expect to continue to incur operating losses in the future, and we may not be able to achieve or sustain future profitability. We have incurred net losses since our inception in 2008. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, we had net losses of $ ~~61~~ **43** . 3 million and $ ~~56~~ **61** . ~~6~~ **3** million, respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~357~~ **400** . ~~1~~ **4** million. We have financed our operations primarily through the net proceeds of our public offerings of our common stock, private placements of equity securities, certain debt- related financing arrangements, and from sales of our products. We have devoted substantially all of our resources to research and development of our products, sales and marketing activities, investments in training and educating surgeons and other healthcare providers, 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 of our product candidates in development, and to transition to profitability and generate consistent positive cash flows ~~, and even if we are able to do so, our ability to do so has been delayed by the COVID- 19 pandemic~~ . 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. 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 expected future capital requirements depend on many factors including expanding our ~~surgeon~~ **physician** base, the expansion of our sales force, investment in implants and instruments, ~~and~~ the timing and extent of spending on the development of our technology to increase our product offerings, and potential investment in additional product and service offerings through the acquisition of other businesses. We may need additional funding for 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. The capital markets have deteriorated substantially since the beginning of 2022, especially with respect to securities issued by companies in the medical device and technology sectors. Equity and debt capital have become substantially more expensive and difficult to raise on attractive terms. 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. Prolonged inflation and supply chain disruptions could result in delayed product launches, lost revenue, higher costs and decreased profit margins. A majority of our products are manufactured and sold inside of the United States, which increases our exposure to domestic inflation and fuel price increases. Recent inflationary pressures have resulted in increased fuel, raw materials and other costs which, if they continue for a prolonged period, may adversely affect our results of operations. We have experienced shortages in certain raw materials and component inputs of our products, primarily surgical instruments, as suppliers have been unable to meet delivery schedules due to excess demand and labor shortages, and lead times have lengthened throughout our supply chain. Our efforts to mitigate supply chain weaknesses may not be successful or may have unfavorable effects. For example, efforts to purchase raw materials in advance for product manufacturing may result in increased storage costs or excess supply. If our costs rise due to continuing significant inflationary pressures or supply chain disruptions, we may not be able to fully offset such higher costs through price increases. In addition, delays in obtaining materials, components or instruments from our suppliers could delay product launches or result in lost opportunities to sell our products due to their availability. Increased costs and decreased product availability due to supply chain issues could adversely impact our revenue and / or gross margin, and could thereby harm our business, financial condition, and results of operation. Disruptions in the supply of the materials and components used in manufacturing our products or the sterilization of our products by third- party suppliers could adversely affect our business, financial condition and results of operations. Our suppliers purchase many of the materials and components used in the manufacture of our products from third-party suppliers. Certain of these materials and components can only be obtained from a single source or a limited number of sources due to quality considerations, expertise, costs or constraints resulting from regulatory requirements. In certain cases, our suppliers may not be able to establish additional or replacement suppliers for such materials or components or outsourced activities in a timely or cost effective manner. A reduction or interruption in the supply of materials or components used in

manufacturing our products, such as due to one or more suppliers experiencing reductions in operations and / or worker absences due to ~~the COVID- 19 pandemic or other~~ health epidemics, an inability to timely develop and validate alternative sources if required, or a significant increase in the price of such materials or components, such as that caused by inflation and rising interest rates, could adversely affect our business, financial condition and results of operations. For example, certain of our products require titanium, which is sourced from third- party suppliers. While the titanium required for such products is not directly sourced from Russia, the current geopolitical events involving Russia and Ukraine are negatively impacting the wider titanium supply chain ~~and such~~ **. These** geopolitical events and **related** factors **and** ~~relating thereto or resulting~~ **results** ~~therefrom~~ , including related sanctions, may negatively impact the ability of our suppliers' third- party supply sources to timely supply titanium to our suppliers and may increase or result in additional costs to us. In addition, many of our products require sterilization prior to sale, and our suppliers use contract sterilizers to perform this service. To the extent that these contract sterilizers are unable to sterilize our products, whether due to capacity, availability of materials for sterilization, regulatory or other constraints, including reductions in operations and / or worker absences due to ~~the COVID- 19 pandemic or other~~ health epidemics, we may be unable to transition to other contract sterilizers, sterilizer locations or sterilization methods in a timely or cost effective manner or at all, which could have a material impact on our results of operations and financial condition. If hospitals, ~~surgeons~~ **physicians** , and other healthcare providers are unable to obtain and maintain adequate or any coverage and reimbursement from third- party payors for procedures performed using our products, further adoption of our products may be delayed, and it is unlikely that they will gain further acceptance, and the prices paid for our implants may decline. Maintaining and growing sales of our products 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, ~~surgeons~~ **physicians** , 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. When a procedure using our implants is performed, both the ~~surgeon~~ **physicians** and the healthcare facility, either a hospital or ambulatory surgical center, submit claims for reimbursement to the healthcare payor. We may be unable to sell our products on a profitable basis if third- party payors deny coverage, or if reimbursement levels are insufficient to support use of our products by healthcare facilities or to compensate ~~surgeons~~ **physicians** for their time spent diagnosing patients and performing procedures using our products **. Even if favorable coverage and reimbursement status is attained for procedures using our implants, less favorable coverage policies and reimbursement rates may be implemented in the future** . While all Medicare Administrative Contractors are regularly reimbursing for minimally invasive sacroiliac joint fusion utilizing laterally placed transfixing devices, a small number of private payors still have policies that treat the procedure as experimental or investigational and do not regularly reimburse for the procedure. **The American** ~~Future action by the Centers for Medicare~~ **Medical Association** ~~and Medicaid Services~~ (**AMA** ~~" CMS "~~) **develops** ~~or third- party payors may further reduce the availability of payments to physicians, outpatient surgery centers,~~ and **maintains** / or hospitals for procedures using our..... placed transfixing iFuse implants, described as Current Procedural Terminology (" CPT ") Code 27279, is $ 827..... (AMA) develops and maintains CPT codes that are used by third- party payors to determine the amount of reimbursement that a healthcare provider and facility will receive for a particular service. CPT codes are divided into three categories: Category I codes represent existing services or procedures that are widely used. Category II codes are supplemental tracking codes, and Category III codes are temporary codes that represent new technologies, services, and procedures. A Category III code does not have a payment rate established and reimbursement is at the payor' s discretion. CPT Code 27279, which describes minimally - invasive surgical fusion of the sacroiliac joint performed with our laterally placed transfixing iFuse implants, is a Category I CPT code **. This CPT code has been clarified to describe procedures in which implants pass through the ilium, go across the sacroiliac joint, and into the sacrum (transfixation)** . As the number of products and surgical procedures to address sacroiliac joint dysfunction has expanded and diversified, certain medical societies requested that the AMA create additional codes representing some of these newer, and different procedures utilizing non- transfixing technologies. ~~In May~~ **Effective January 1,** ~~2022~~ **2024** , the AMA CPT Editorial ~~Panel~~ **panel** adopted **an additional** ~~a proposal for a new~~ Category ~~III~~ **I** code ~~to become effective January 1~~ , ~~2023~~ **CPT Code 27278** , **to** ~~describing~~ **describe** ~~a different sacroiliac joint procedure~~ **procedures using** ~~to place interpositional,~~ intra- articular ~~and~~ **,** non- transfixing implants ~~typically using a dorsal~~ , **including bone allograft products and / or metal plugs. Effective January 1, 2024, the Medicare physician fee reimbursement** ~~or~~ **for** ~~posterior~~ **minimally invasive fusion with our laterally placed transfixing iFuse implants** , **described as** ~~approach. In September 2022, the AMA~~ CPT ~~Editorial Panel subsequently approved a proposal to create another Category III tracking code~~ **Code 27279** ~~to describe the implantation of both lateral transfixing implants~~ , ~~as well as~~ **is $ 791; and for our** intra- articular ~~(dorsal, or~~ non- transfixing **iFuse implants, described as CPT 27278, the Medicare physician fee is $ 459 when performed in the facility setting, and $ 11, 934 when performed in the physician office (e. g., office- based lab**) **setting. Minimally invasive** ~~implants during the same operative session (" hybrid "~~ sacroiliac **fusion performed with a transfixing device is not eligible for the office- based lab site- of- service and there is therefore no corresponding value for office- based reimbursement for CPT** Code 27279 ~~,is $ 827~~ .Commercial payors generally set their physician fee reimbursement with reference to Medicare reimbursement rates.We believe that some ~~surgeons~~ **physicians** may continue to view the Medicare and commercial reimbursement amounts as insufficient for the **lateral** procedure **described by CPT Code 27279** ,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 if necessary.We believe that some private payors apply their own coverage policies and criteria inconsistently,and ~~surgeons~~ **physicians** may not be able to consistently have minimally invasive sacroiliac fusion ~~procedures utilizing laterally placed transfixing devices approved and covered.The perception by physicians that the reimbursement for minimally invasive sacroiliac joint fusion is insufficient to compensate them for the work required,including diagnosis,~~ procedures **utilizing laterally placed transfixing devices approved** ~~) effective July 1, 2023;~~ and ~~also voted to convert~~ **covered. The perception by**

physicians performing the ~~Category III~~ **lateral procedure described by CPT** Code **27279 that the reimbursement for minimally invasive sacroiliac joint fusion is insufficient** to ~~describe~~ **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 adversely affect our revenues** ~~to implant the newer, non-transfixing (dorsally placed) implants to a Category I Code effective January 1, 2024~~ . If the levels of reimbursement for, and consistency of coverage associated with, procedures performed with our medical devices under ~~the existing Category I~~ CPT Code **27279** ~~decrease~~ **decreases** as a result of or in connection with these coding changes, it could make the procedures in which our implants are used less attractive to healthcare professionals, decreasing the number of devices we are able to sell and adversely affecting our business, results of operations and financial condition ~~Medicaid Services (" CMS ") or third- party payors may reduce the availability of payments to physicians,outpatient surgery centers,and~~ / or hospitals for procedures using our products.Volatility in the payment rates that physicians and hospitals receive from CMS may have a material impact on their willingness to perform procedures including our products,as well as place additional pressure on pricing of our implants.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.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 **.Effective January 1,2023,the Medicare physician fee reimbursement for minimally invasive fusion with our laterally placed transfixing iFuse implants,described as** . Recent political, economic, and regulatory influences are subjecting the healthcare industry to fundamental changes that can impact coverage and reimbursement from third- party payors. We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2011, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products. **In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (" IRA ") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. Further,** CMS budget neutrality requirements may impose cuts to the Medicare physician fee schedule, which may be mitigated by acts of Congress or other changes to regulations. Other federal laws, known as budget sequestration, further reduce Medicare' s payments to providers **by** ~~. Under current legislation, the reduction in Medicare payments will vary from~~ 2 % **, which, due** ~~under the Budget Control Act of 2011 (currently set~~ to ~~expire~~ **subsequent legislative amendments, will stay** in **effect through** ~~2031~~ **2032** ~~) to 4 % if budget sequestration is triggered under the Statutory Pay- As- You- Go Act of 2010~~ . These reductions may reduce reimbursement for procedures performed using our products, which could potentially negatively impact our revenue, and may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Both the federal and state governments in the **United States** ~~U. S.~~ and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry- wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales, which could adversely affect our business, results of operations and financial condition. Market acceptance of our products in foreign markets may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government- sponsored healthcare and private insurance. We may not obtain additional international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought. If healthcare payors reverse decisions to cover minimally invasive sacroiliac joint fusion exclusively when performed with iFuse **triangular implants** and choose to reimburse for procedures performed with competitive products, our market share **and average selling prices** could decline, adversely affecting our revenues. As of December 31, ~~2022~~ **2023** , a significant number of the largest U. S. payors that we track and target have issued positive coverage policies covering the patented design of our triangular iFuse implants and excluding coverage of other products that are intended to fuse the sacroiliac joint because of the clinical evidence supporting the use of triangular titanium implants and the lack of clinical evidence supporting the use of other products. We believe that payors have adopted these exclusive coverage decisions due to the strength of our clinical evidence and in part due to recommendations of specialty benefit managers and healthcare technology assessment organizations. Clinical trials of the type and size necessary to offer evidence of the safety and efficacy of competing products could be performed and could show that other products for sacroiliac joint fusion are as effective as, or more effective than, our triangular iFuse implants. Payors could also abandon their decisions to cover triangular implants exclusively for other reasons. Healthcare payors which have adopted sacroiliac joint fusion coverage policies exclusive to titanium triangular implants could reverse the exclusive nature of their policies and allow ~~surgeons~~ **physicians** to use other types of products when performing sacroiliac fusion procedures **. Some payor have removed such exclusivity in the past and others could do so in the future** . For example, AIM, a clinical evidence evaluation organization which influences Anthem, among other payors, promulgated such a policy, effective September 11, 2022, that is no longer exclusive to titanium triangles. If healthcare payors covering a significant number of covered lives reverse their policies of covering minimally invasive sacroiliac joint fusion exclusively when performed with triangular titanium implants, ~~sales~~ **the average selling price** of our triangular iFuse implants could decline **and**

their sales could decline or fail to grow **. If physicians choose to substitute our triangular iFuse implants with competitors' products** , ~~which~~ **this** could adversely affect our business, results of operations and financial condition. Epidemic diseases, or the perception of their effects, may continue to adversely affect our business, financial condition, results of operations, or cash flows. **The** ~~As the COVID- 19 global pandemic enters its fourth year, the~~ impact of COVID- 19 on our business remains highly dependent on future developments, which are uncertain and unpredictable. ~~An~~ **Although the U. S. public health emergency ended on May 11, 2023, an** outbreak of an infectious disease, or ~~an~~ **a re-** escalation of ~~the~~ COVID- 19 ~~pandemic~~ **infection rates** could ~~continue to~~ divert medical resources toward the treatment of that disease, and negatively affect hospital admission rates and the decision by patients to undergo elective surgery, which could decrease demand for procedures using our implants and cause other disruptions to our business. Business disruptions have included, and could continue to include, disruptions or restrictions on our ability to travel or to distribute our products, government orders suspending the performance of elective surgical procedures, 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 suppliers and their 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~~ **regional or global** economic ~~downturn~~ **downturns** that could affect demand for our products **, as well as increase risk of customer defaults or delays in payments** . Any of these events could negatively impact the number of procedures using our implants that are performed and have a material adverse effect on our business, financial condition, results of operations, ~~or~~ cash flows ~~. 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~~ **or** ~~our products as well as increase 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 herein **. Natural disasters and man- made business disruptions such as war and terrorism could seriously harm our future revenue and financial condition and increase our costs and expenses. We operate our business in regions subject to natural and man- made disasters or business interruptions. Our corporate headquarters are located in Santa Clara, California, a region which has experienced and will continue to experience earthquakes, fires, power shortages, telecommunications failures, water shortages, floods, shifting climate patterns, and extreme weather conditions. We also rely on third- party manufacturers to produce our products and on third- party logistics companies to transport our products. A major earthquake, fire, tornado, blizzard or other disaster (such as a flood, storm, drought or terrorist attack) could significantly disrupt our operations, ranging from production and shipping delays to lost revenue and increased costs. The occurrence of any of these natural or man- made disasters or other business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Additionally, if our facilities or any of our customers' facilities are negatively impacted by a disaster, procedures using our products could be delayed or canceled. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts or brownouts, which could disrupt the operations of our affected facilities and harm our business. Further, concerns about terrorism, the effects of a terrorist attack, or political turmoil could have a negative effect on our operations, those of our suppliers and customers, and the ability to travel, which could harm our business, financial condition, and results of operations** . We may not be able to convince physicians that our products are attractive alternatives to our competitors' products and that our procedures are attractive alternatives to existing surgical and non- surgical treatments for their respective indications. ~~Surgeons~~ **Physicians** , in consultation with their patients, play the primary role in determining the course of treatment and, ultimately, any product that will be used in treatment. **For** ~~In order for~~ us to sell our products successfully, we must demonstrate to ~~surgeons~~ **physicians** through education and training that treatment with iFuse is beneficial, safe, and cost- effective for patients as compared to our competitors' products. If we are not successful in demonstrating the merits of our products to ~~surgeons~~ **physicians** , their use of our products may decline, adversely affecting our revenues and profitability. Historically, **many physicians** ~~most spine surgeons~~ did not include an evaluation of the sacroiliac joint in their diagnostic work- up because they did not have an adequate surgical procedure to perform for patients diagnosed with sacroiliac joint dysfunction. We believe that educating ~~surgeons~~ **physicians** and other healthcare professionals about the clinical merits and patient benefits of iFuse is an important element of building our business. If we fail to effectively educate ~~surgeons~~ **physicians** and other medical professionals, they may not include a sacroiliac joint evaluation as part of their diagnosis and, as a result, those patients may continue to receive unnecessary surgical procedures or only non- surgical treatment. ~~Surgeons~~ **Physicians** 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~~ **our** products and procedures; • costs associated with the purchase of ~~new~~ **our** products; and • time commitment that may be required for training. Furthermore, we believe ~~surgeons~~ **physicians** will not widely use our products unless they determine, based on experience, clinical data, and published peer- reviewed publications, that ~~surgical intervention provides benefits or~~ **our** ~~is~~

products offer an attractive alternative to non- surgical treatments of sacroiliac joint dysfunction. In addition, we believe support ~~of~~ **for** our products relies heavily on long- term data showing their benefits. If we are unable to provide that data, ~~surgeons~~ **physicians** may not use our products. In such circumstances, we may not achieve expected sales and may be unable to achieve profitability. ~~Many~~ **We believe that training is particularly important in instances of newly launched products or the introduction of a product into a new market. If physicians are not properly trained, they may misuse our products, which may result in unsatisfactory** ~~patients~~ **patient outcomes, patient injury, negative publicity, or lawsuits against us. In addition, a failure to educate the medical community regarding our products may impair our ability to achieve market acceptance of our products. Patients** with sacroiliac joint dysfunction are cared for by **a variety of health care providers, including spine surgeons and** pain physicians and other ~~interventionalists~~ **interventionalist spine physicians**, who are generally trained as anesthesiologists **, interventional radiologists,** or physical medicine and rehabilitation specialists. These ~~physicians~~ **interventionalists** often offer a variety of non- surgical and surgical interventions to sacroiliac joint dysfunction patients, including, but not limited to, steroid injections, radiofrequency ablation of the nerves serving the sacroiliac joint **,** and implantation of neurostimulation devices, allografts, **fusion devices** and other products intended to treat the sacroiliac joint or the pain it can cause. Our professional education program seeks to teach these physicians, and other health care providers, about the benefits of **our** iFuse **products** , **with** ~~in order to prompt these~~ **the** ~~providers to~~ **intent of either having them adopt and perform our procedures or** refer their patients with sacroiliac joint dysfunction to ~~surgeons~~ **physicians** who have been trained to perform **our** ~~the iFuse procedure~~ **procedures** . ~~These providers~~ **Providers who have not been educated on or adopted our procedures** may ~~, however,~~ prefer to continue to treat these patients with ~~the~~ **other** interventions they offer because ~~they feel~~ **of physician preference or their view** that these interventions are superior ~~or because~~ **. Effective January 1, 2024,** ~~they~~ **the** ~~have~~ **AMA CPT Editorial Panel introduced** a ~~financial interest in~~ **new permanent Category 1 CPT Code, 27278, to describe minimally invasive sacroiliac fusion achieved with placement of an intra- articular implant, typically from a posterior approach, and without the use of a transfixing device. While we** ~~offering~~ **offer** ~~additional treatments~~ **products that can be used in procedures described by both CPT Codes 27278 and 27279, historically our primary focus has been on products used in procedures described by CPT Code 27279. If more physicians elect** to ~~these~~ **offer, or more** patients ~~. If~~ **elect to undergo, procedures described by CPT Code 27278, or if** we are unable to demonstrate to **physicians** ~~potential referring health care providers~~ the comparative benefits of **our products** ~~iFuse, and we are therefore unable to prompt sufficient numbers of these providers to refer their patients with sacroiliac joint dysfunction for treatment by surgeons trained to perform the iFuse procedure~~ , sales of our iFuse implants could decline or fail to grow, which could adversely affect our business, results of operations and financial condition. ~~Surgeons~~ **Physicians** and payors may not find ~~our~~ **the** clinical evidence **supporting our more recent products** to be compelling, which could limit our sales and revenue, and on- going and future research may prove our products to be less safe and effective than currently thought. The products we currently market in the United States have either received premarket clearance under Section 510 (k) of the United States Federal Food, Drug, and Cosmetic Act (" FDCA "), or are exempt from premarket review. Those marketed in the **EEA** ~~European Union (" EU ")~~ have been the subject of a CE Certificate of Conformity. The 510 (k) clearance process of the U. S. Food and Drug Administration (" 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 (" PMA "), and does not usually require pre- clinical or clinical studies. As a result, ~~while there are a number of published studies relating to~~ iFuse **- TORQ** and **iFuse Bedrock Granite have been launched prior to gathering substantial prospective clinical trial evidence** ~~minimally invasive sacroiliac joint surgery that support the safety and effectiveness of our products and the benefits they offer~~ , **and** our **post- market** clinical studies may lack the size and scope of randomized controlled clinical trials required to support approval of a PMA. For these reasons, ~~surgeons~~ **physicians** may be slow to adopt our products, 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 products does not improve patient outcomes. Such results would slow the adoption of our products by ~~surgeons~~ **physicians** , significantly reduce our ability to achieve expected sales, and could prevent us from achieving profitability. Pricing pressure from our competitors, changes in third- party coverage and reimbursement, healthcare provider consolidation, ~~payor consolidation and~~ the presence of ~~"~~ physician- owned distributorships ~~"~~ **, and payor consolidation** 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 maintain and grow our market share. The sacroiliac joint fusion market has attracted numerous new companies and technologies. As a result of this increased competition, we believe there will be continuing increased pricing pressure, resulting in lower gross margins, with respect to our products. 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 products, discounts, and number of implants used may also drive our prices and revenue down and harm our ability to market and sell our products. 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 prices of our products, 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. Practice trends **, market dynamics,** or other factors, including the COVID- 19 pandemic, have caused, and may continue to cause, procedures to shift from the hospital environment to ambulatory surgical centers, or ASCs, where pressure on the prices of our products is generally more acute. We anticipate that more outpatient eligible procedures will be performed in ASCs **to** ~~as a cost~~ control ~~measure within the healthcare system~~ **costs and expand patient access to medical procedures** . This shift accelerated during the COVID- 19 pandemic, and we expect it to continue because ASCs are generally a more economically favorable site of service, and ~~surgeons~~ **physicians** performing the procedures sometimes have ownership interests in the ASC. Because ASC facility fee reimbursement is typically less than facility fee reimbursement for hospitals and due to ~~surgeons~~ **physicians** ' economic interest in ASCs, 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. In addition, some ~~surgeons~~ **physicians** may choose to use fewer implants due to their interest in the profitability of the ASC. An accelerated shift of procedures using our products to ASCs could adversely impact the average selling prices of our products and our revenues could suffer as a result. 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 adversely affected. Our currently marketed products are, and any future products we commercialize will likely be, subject to intense competition. Our field is subject to rapid change and is 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 viewed as 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, other companies have dedicated, and likely will continue to dedicate, significant resources to developing competing products. The number of competitors that we are aware of marketing sacroiliac joint fusion products in the United States has grown since 2008. Some of our current and potential 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 products obsolete or noncompetitive. In addition, many of these competitors have significantly longer operating history and more established reputations than we do. Some of these companies sell a broad suite of products that can be used together in the operating room in order to facilitate surgery, such as surgical imaging, navigation and robotic systems, or a large number of implants intended to treat different conditions affecting the spine and pelvis. The ability of these competitors to sell these products together or as part of larger purchasing arrangements may put us at a disadvantage. In addition, if these competitors use technology, contracts, or intellectual property measures to limit or eliminate the compatibility of their surgical imaging, navigation and robotic systems with our products, sales of our products could decline or fail to grow, which could adversely affect our business and results of operations. In the United States, we believe that our primary competitors marketing implantable devices currently are Globus Medical, Inc. and Medtronic plc. Our primary competitors in Europe are Globus Medical, Inc. and SIGNUS Medizintechnik GmbH. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of the sacroiliac joint that compete directly or indirectly with our products. They may also develop and patent processes or products earlier than we can, or obtain domestic and international regulatory clearances or approvals and CE Certificates of Conformity for competing products in the ~~European Economic Area (" EEA ")~~ , more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products and our results of operations could be negatively affected. 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 current or planned future products may make it difficult to differentiate the benefits of our products 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 products and pricing in the market generally. In addition, a number of companies selling allograft implants for use by a variety of physicians have collectively become a much larger presence in our market. If customers view allograft implants and our ~~products~~ **titanium implants** as interchangeable, we risk increased pricing pressure on our products. It is unclear how the ~~creation of the Category III code for these procedures effective January 1, 2023, and the conversion of the Category III Code to a~~ Category I Code **27278** effective January 1, 2024, will impact the market for these products and procedures. As a result, without the timely introduction of new products and enhancements, our products may become obsolete over time. If we are unable to develop innovative new products, maintain competitive pricing, and offer products that surgeons and other physicians perceive to be as reliable as those of our competitors, our market share or product margins could decrease, thereby harming our business. We are highly dependent on revenue from the sale of a single family of products focused on procedures, the goal of which is to stabilize and fuse the sacroiliac joint. Reliance on a single family of products and single family of procedures could negatively affect our results of operations and financial condition Substantially all of our revenue comes from the sale of iFuse, iFuse- 3D, iFuse- TORQ, and iFuse Bedrock Granite implants, and related tools and instruments. Therefore, we are dependent on widespread market adoption of iFuse and we will continue to be dependent on the success of this single product family for some time. There can be no assurance that iFuse will maintain a substantial degree of market acceptance among ~~surgeons~~ **physicians** , patients or healthcare providers. Our failure to successfully grow the market for iFuse and increase our share within that market or any other event impeding our ability to sell iFuse, could adversely affect

our results of operations, financial condition and continuing operations. If clinical experience with our iFuse Bedrock technique ~~or ,~~ iFuse Bedrock Granite **product, or iFuse- TORQ product** does not result in positive outcomes for patients, or if clinical trials involving the use of iFuse Bedrock **,** ~~and / or~~ iFuse Bedrock Granite **and / or iFuse- TORQ** fail to show meaningful patient benefit, sales of our iFuse, iFuse- 3D, iFuse- TORQ and / or iFuse Bedrock Granite implants could be adversely impacted. In November 2018, we introduced our iFuse Bedrock technique, in which spine surgeons place iFuse triangular implants across the sacroiliac joint using a different surgical approach to treat sacroiliac joint dysfunction at the same time they are fusing multiple levels of the spine above and affixing those spinal fusion devices to the pelvis. In April 2019, the FDA cleared promotion of iFuse Bedrock for a broader and more general purpose, to provide additional stability and immobilization of the sacroiliac joint in connection with a thoracolumbar fusion procedure. In May 2022, we introduced iFuse Bedrock Granite, an implant which fuses the sacroiliac joint and attaches to the rods placed in a multi- segment spinal fusion construct, and which is used in substantially similar procedures as the iFuse Bedrock technique. To date, clinical experience with the iFuse Bedrock technique and with iFuse Bedrock Granite is limited and we have yet to complete a clinical trial to evaluate the iFuse Bedrock technique or the iFuse Bedrock Granite implant. Surgeons do not know if the addition of sacroiliac fusion devices to the implants used to fuse multiple levels of the lumbar spine will result in patient benefit. If surgeons' clinical experience with our implants in these procedures is not positive, or if our clinical trials do not show meaningful benefits to the patients undergoing this procedure, sale of our iFuse implants for this indication could be adversely impacted, which could negatively affect our operations and financial condition. **In February 2021, we launched iFuse- TORQ, a line of 3D- printed threaded implants designed for use in pelvic trauma, as well as applications in sacroiliac joint dysfunction and degeneration. In 2022, the FDA provided clearance for an expanded indication for iFuse- TORQ to include acute, non- acute and non- traumatic fractures as well as for placement across the sacroiliac joint using our Bedrock technique. Clinical experience with iFuse- TORQ is limited and we have yet to complete a clinical trial to evaluate the use of iFuse- TORQ in patients with sacral fragility or insufficiency fractures. Physicians do not yet know if pelvic fracture fixation and sacroiliac joint fusion using iFuse- TORQ is superior to nonsurgical management in this class of patients. If physicians' clinical experience with our implants in these procedures is not positive, or if our clinical trials do not show meaningful benefits to the patients undergoing this procedure, sale of our iFuse implants for this indication could be adversely impacted, which could negatively affect our operations and financial condition.** If we are unable to maintain our network of direct sales representatives ~~and ,~~ third- party ~~distributors~~ **sales agents, and resellers** , we may not be able to generate anticipated sales. As of December 31, ~~2022~~ **2023** , our U. S. sales force consisted of ~~88~~ **82** territory sales managers and ~~73~~ **69** clinical support specialists directly employed by us and ~~105~~ **175** third- party ~~distributors~~ **sales agents** . As of December 31, ~~2022~~ **2023** , our international sales force consisted of ~~18~~ **14** sales representatives directly employed by us and ~~30 exclusive~~ **a total of 31** third- party ~~distributors~~ **sales agents and resellers** , which together have had sales in 38 countries through December 31, ~~2022~~ **2023** . Our operating results are directly dependent upon the sales and marketing efforts of both our direct sales force and of our third- party ~~distributors~~ **sales agents and resellers** . As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives and third- party ~~distributors~~ **sales agents and resellers** with significant technical knowledge in various areas, such as spine and pelvic health and treatment. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. If a direct sales representative or third- party ~~distributor~~ **sales agent or reseller** departs and is retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. The launch of new products or entrance into new markets could distract our sales representatives from existing customers and markets and redirect resources from existing to novel markets. Furthermore, any such change affects our ability to hire, contract with and retain members of our direct sales force and third- party ~~distributors~~ **sales agents and resellers** . Because of the intense competition for their services, we may be unable to recruit or retain additional qualified third- party ~~distributors~~ **sales agents and resellers** or to hire additional direct sales representatives to work with us. Furthermore, we may not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified direct sales representatives or third- party ~~distributors~~ **sales agents and resellers** would prevent us from expanding our business and generating sales. If our direct sales representatives or third- party ~~distributors~~ **sales agents** fail to adequately promote, market and sell our products or decide to leave or cease to do business with us, our sales could significantly decrease. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would 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 limited 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. Our business is highly reliant on a base of skilled employees, including those serving in engineering, information technology, operational, strategic marketing and sales functions. Many of these employees have developed specialized skills which are valuable within the medical device and life sciences industry, and, in some cases, in a broader variety of industries. Competition for skilled employees ~~is~~ **remains** significant **. If** ~~, and some of the labor markets~~ we ~~compete in have experienced tightening in the past~~

~~year. In addition, rates of employee turnover have increased among our employees, consistent with the rates experienced by other companies in these industries. If these conditions persist, we could~~ experience ~~further~~ turnover among our employees ~~which~~ **at a higher rate than expected, managing our labor force** could become difficult and more costly ~~to manage~~, adversely impacting our results of operation. Sustained pressure in these labor markets could also cause prevailing wages to rise, which could adversely impact our business, results of operation and financial condition. If use of our products results in adverse events, this may require them to be taken off the market, require them to include safety warnings or otherwise limit their sales. Unforeseen adverse events related to our products could arise either during clinical development or, if cleared, approved, or subject to CE Certificate of Conformity **and CE marked**, after the product has been marketed. In clinical research, the most common adverse event related to our implant was leg pain resulting from misplacement. The most common adverse event for our implant procedure has been minor wound infections. Additional adverse effects from iFuse or any of our other products could arise either during clinical development or, if approved, cleared, or subject to CE Certificate of Conformity **and CE marked**, after the product has been marketed. If we or others later identify adverse events caused by our products: • sales of the product may decrease significantly, and we may not achieve the anticipated market share; • regulatory authorities or our Notified Body may require changes to the labeling of our product. This may include the addition of labeling statements, specific warnings, and contraindications and issuing field alerts to physicians and patients; • we may be required to change instructions regarding the way the product is implanted or conduct additional clinical trials; • we may be subject to limitations on how we may promote the product; • regulatory authorities may require us to temporarily or permanently take our approved product off the market or to conduct other field safety corrective actions **; • our Notified Body may suspend, amend, or withdraw our CE Certificate of Conformity or refuse or delay any ongoing applications relating to the issuance or renewal of CE Certificates of Conformity**; • we may be required to modify our product; • we may be subject to litigation fines or product liability claims; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products. Unfavorable media reports or other negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our products. ~~We introduced~~ iFuse Bone ~~,~~ **is** an implantable bone product manufactured from sterilized recovered cadaveric bone tissue ~~, to meet the demand of some of our surgeon customers to use implantable bone products to support and augment the patient's own bone tissue in orthopedic procedures~~. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to the transmission of disease, may affect the rate of future tissue donation and market acceptance of technologies incorporating human tissue. In addition, negative publicity could cause the families of potential donors to become reluctant to donate tissue to for- profit tissue processors. These reports could have a negative effect on sales of iFuse Bone. Various factors outside our direct control may adversely affect manufacturing, sterilization, and distribution of our products. The manufacture, sterilization, and distribution of our products is challenging. Changes that our suppliers may make outside the purview of our direct control can have an impact on our processes, quality of our products, 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 complete sterilization on time or in compliance with the required regulatory standards; • transportation and import and export risk; • delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products; • large- scale epidemics of communicable diseases such as COVID- 19; • supply chain disruptions, including those caused by material and labor supply shortages **and prolonged inflation** ~~in the wake of COVID- 19~~; • 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 suppliers; and • latent defects that may become apparent after products have been released and that may result in a recall or field safety corrective action with respect to such products. If any of these risks were to materialize, our ability to provide our products to customers on a timely basis could be adversely impacted. We are dependent on a limited number of third- party suppliers, some of them single- source and some of them in single locations, for most of our products and components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials in a timely and cost- effective manner, could materially adversely affect our business. We rely on third- party suppliers to manufacture and supply substantially all of our products. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable prices, and on a timely basis. We do not have long-term supply contracts for some of our suppliers, and in some cases, even where we do have agreements in place, we purchase important parts of the iFuse Implant System, including our implants, from a single supplier. Therefore, we cannot assure investors that we will be able to obtain sufficient quantities of product in the future. In addition, future growth could strain the ability of our suppliers to deliver products, materials, and components. Suppliers often experience difficulties in scaling up production, including financial issues, or problems with production yields and quality control and assurance. For example, from time to time, we have experienced certain delays and may experience delays from our suppliers in the future. We generally use a small number of suppliers for our instruments and currently rely on RMS for iFuse- 3D **and iFuse- TORQ** implants and Orchid for iFuse implants. Our dependence on such a limited number of suppliers exposes us to risks, including, among other things: • third- party contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the safety or effectiveness of our products or cause delays in shipments of our products; • third- party contract manufacturers or suppliers may fail to maintain good manufacturing practices, leading to quality control problems or regulatory findings that could cause disruptions in their manufacturing processes and **affect the safety or effectiveness of our products or cause or** lead to delays in shipments of our products; • we or our third- party manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we

or our suppliers may have excess or inadequate inventory of materials and components; • we or our third- party manufacturers and suppliers may be subject to price fluctuations due to a lack of long- term supply arrangements for key components; • we or our third- party manufacturers and suppliers may lose access to critical services, raw materials and components, or experience significant delays in obtaining them, resulting in an interruption in the manufacture, assembly and shipment of our systems; • we or our third- party manufacturers could experience plant closures due to local epidemics of communicable diseases, such as COVID- 19, or local outbreaks of such diseases among their workforce, thereby shuttering a plant in which our products are manufactured; • we may experience delays in delivery by our third- party manufacturers and suppliers due to changes in demand from us or their other customers; • fluctuations in demand for products that our third- party manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner; • our third- party manufacturers and suppliers may wish to discontinue supplying components or services to us for risk management reasons; • we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and • our third- party manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements. If any one or more of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our products and to launch new products. If we are unable to satisfy commercial demand for our system in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products 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. In addition, most of our supply and manufacturing agreements do not have minimum manufacturing or purchase obligations. As such, with many of our suppliers, we have no obligation to buy any given quantity of products, and the suppliers have no obligation to sell us or to manufacture for us any given quantity of components or products. As a result, our ability to purchase adequate quantities of components or our products may be limited and we may not be able to convince suppliers to make components and products available to us in some instances. Our suppliers may also encounter problems that limit their ability to supply components or manufacture products for us, including financial difficulties, damage to their manufacturing equipment or facilities, product discontinuations or adverse findings in quality audits. As a result, there is a risk that certain components could be discontinued and no longer available to us. We may be required to make significant " last time " purchases of component inventory that is being discontinued by the supplier to ensure supply continuity. If we fail to obtain sufficient quantities of high quality components to meet demand for our products in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Securing a replacement third- party manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to our iFuse system that are subject to domestic and international regulatory clearances or approvals and the review of our Notified Body. Because of the nature of our internal quality control requirements, regulatory requirements, and the custom and proprietary nature of the parts, we may not be able to quickly engage additional or replacement suppliers for many of our critical components. We may also be required to assess any potential new manufacturer' s compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our products, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Failure of any of our third- party suppliers 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 components from other suppliers that are acceptable to the FDA, ~~our Notified Body and the competent authorities in the countries of the EEA, or~~ other foreign regulatory authorities, **or applicable QMS requirements** and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to delays in obtaining clearances ~~or~~ approvals **or CE Certificates of Conformity** , regulatory action including warning letters, product recalls, termination of distribution **, operating restrictions, interruption of production, delays in the introduction of products into the market** , product seizures, civil, administrative, or criminal penalties and the suspension, variation, or withdrawal of our CE Certificates of Conformity. We could incur delays while we locate and engage qualified alternative suppliers, and we may be unable to engage alternative suppliers 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, each of our third- party suppliers operates at a facility in a single location and substantially all of our inventory of component supplies and finished goods is held at these locations. A local outbreak of COVID- 19 cases, vandalism, terrorism, or a natural or other disaster, such as an earthquake, fire, or flood, could damage or destroy equipment or our inventory of component supplies or finished products, 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 suppliers' facilities could harm our business, financial condition, and operating results. We may encounter problems or delays in the assembly of our products or fail to meet certain regulatory requirements which could result in an adverse effect on our business and financial results. To become profitable we must assemble our products in adequate quantities in compliance with regulatory requirements and at an acceptable cost. Increasing our capacity to assemble and test our products will require us to improve internal efficiencies. We may encounter a number of difficulties in increasing our assembly and testing 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. If we are unable to satisfy commercial demand for our products due to our inability to assemble and test, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected and customers may instead purchase or use our competitors' products. If we do not enhance and broaden our product offerings through our research and development efforts, we may be unable to compete effectively. In order to increase our market share in the sacroiliac joint fusion and related markets, we must enhance and broaden our product offerings in response

to customer demands and competitive pressures and technologies. We might not be able to successfully develop, obtain domestic and international regulatory clearances or approvals, or CE Certificates of Conformity for, or market new products, and our future products might not be accepted by the ~~surgeons~~ **physicians** or the third- party payors who reimburse for many of the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to: • properly identify and anticipate ~~surgeon~~ **physician** and patient needs; • develop and introduce new products or product enhancements in a timely manner; • create sufficient product differentiation to expand overall market share and minimize cannibalization of existing product markets; • **obtain and maintain adequate coverage from third- party payors for new products or procedures; • mitigate downward pricing pressure on new and existing products; •** adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; • demonstrate the safety and effectiveness of new products; and • **provide sufficient infrastructure needed** ~~obtain the necessary domestic and international regulatory clearances or approvals and CE Certificates of Conformity~~ for ~~new products or~~ product ~~enhancements~~ **commercialization** . If we do not develop and obtain domestic and international regulatory clearances or approvals and CE Certificates of Conformity for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our business could be adversely affected. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or other innovation. In some cases, following a successful product development effort, we may need to invest substantial resources in surgical instrumentation and implant inventory, prior to launch of the product, and before we understand the demand for such product. If we overestimate the demand for such products and invest too heavily in inventory to support the product line, the additional revenue and product margins may not produce a positive return on such investments, which could cause our financial results to suffer. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features. We are required to maintain adequate levels of inventory, the failure of which could consume our resources and reduce our cash flows. As a result of the need to maintain adequate levels of inventory, we are subject to the risk of inventory obsolescence. Many of our products come in sets, which feature components in a variety of sizes so that the implant or device may be chosen for size based on the patient' s needs. In order to market our products effectively, we often maintain and provide ~~surgeons~~ **physicians** and hospitals with back- up products and products of different sizes. For each surgery, fewer than all of the components of the set are used, and therefore certain portions of the set may become obsolete before they can be used. In addition, as we introduce new implants and instruments with the same intended uses as existing products, the older products may fall out of favor with our customers, causing them to become obsolete. In **addition, market demand for our new products may be less than expected, resulting in excess inventory from the supply purchased for launch. For example, in the quarter ending December 31, 2023 we took a $ 1. 7 million in reserves for excess inventory related to the" lag" configuration of our iFuse- TORQ product, reflecting its below- expected market demand. In** the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. The size and future growth in the market for ~~our~~ **minimally invasive sacroiliac fusion performed with a lateral approach, such as the** iFuse ~~products~~ **procedure,** has not been established with precision and may be smaller than we estimate, possibly materially. In addition, we estimate cost savings to the economy and healthcare system as a result of the iFuse procedure based on our market research. If our estimates and projections overestimate the size of this market or these benefits and 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 ~~our iFuse products~~ **invasive sacroiliac fusion performed using a lateral approach** or cost savings as a result of the ~~iFuse~~ procedure. Therefore, our estimates of the size and potential for future growth in the market for our iFuse products, cost savings to patients, the healthcare system and the economy overall from its use, and the number of people currently suffering from lower back pain who may benefit from and be amenable to our iFuse 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 iFuse products 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. The actual incidence of lower back pain, and the actual demand for our products 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 iFuse products may prove to be incorrect. In addition, actual health cost savings to the healthcare system as a result of the iFuse procedure may materially differ from those we expect. If the actual number of people with lower back pain who would benefit from our iFuse products and the size and future growth in the market for iFuse products and related costs savings to the healthcare system is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. Our results of operations could suffer if we are unable to manage our international business effectively. Expansion into international markets is an element of our business strategy and involves risk. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U. S. and foreign governmental trade, import, and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non- compliance. Other laws and regulations that can significantly affect us include various anti- bribery laws, including the U. S. Foreign Corrupt Practices Act (" FCPA "), and the United Kingdom Bribery Act (" UKBA "), anti- boycott laws, anti- money laundering laws, and regulations relating to economic sanctions imposed by the **United States** ~~U. S.~~ , including the Office of Foreign Asset Control of the U. S. Treasury. Any failure to comply with applicable legal and regulatory obligations in the **United States** ~~U. S.~~

or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. In addition, some of the countries in which we sell or plan to sell our products are, to some degree, subject to various risks, including: • exposure to different legal and regulatory standards; • lack of stringent protection of intellectual property; • inability of the local healthcare system to absorb prices for our product that would enable our business to become profitable in those markets; • obstacles to obtaining domestic and foreign export, import, and other governmental approvals, permits, and licenses and compliance with foreign laws **; • lower average selling prices of our implants in most foreign markets; • reliance on a more concentrated surgeon base in international markets due to the surgeon acquisition costs relative to the selling price of our implants** ; • potentially adverse tax consequences and the complexities of foreign value- added tax systems; • adverse changes in tariffs and trade restrictions; • limitations on the repatriation of earnings; • difficulties in staffing and managing foreign operations; • insufficient numbers of patients requiring procedures that use our products; • transportation delays and difficulties of managing international distribution channels; • longer collection periods and difficulties in collecting receivables from foreign entities; • increased financing costs; • currency risks; and • political, social, and economic instability and increased security concerns. These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Our successful conduct of our international business depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we plan to do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. In the future our products 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 our iFuse system or that would render the iFuse system obsolete or noncompetitive. 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 changes in technology and the practice of medicine 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 rely on our information technology systems to effectively manage: • sales and marketing, accounting, and financial functions; • customer relationship management; • inventory management; • compliance and regulatory reporting requirements; • 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 or internal or external breaches of our cybersecurity; • power losses; and • computer systems, internet, telecommunications, or data network failures. 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. Like other public companies, we have in the past, and in the future could be subject to instances of phishing attacks on our email systems, other cyber- attacks, industrial espionage, insider threats, computer denial- of- service attacks, computer viruses, ransomware and other malware, wire fraud or other cyber incidents. The techniques used to obtain unauthorized access, or to sabotage systems, are becoming more sophisticated, frequent and adaptive, and therefore we may be unable to anticipate these techniques or to implement adequate preventative measures. Any security breach could result in: the unauthorized publication of our confidential business or proprietary information; the unauthorized release of employee, customer or vendor data and payment information; a loss of confidence by our customers; damage to our reputation; a disruption to our business; litigation and legal liability; and a negative impact on our future sales. In addition, the cost and operational consequences of implementing further data protection or data restoration measures could be significant. In addition, we accept payments for many of our sales through credit card transactions, which are handled through third- party payment processors. As a result, we are subject to a number of risks related to credit card payments. As a result of these transactions, we pay interchange and other fees, which may increase over time and could require us to either increase the prices we charge for our products or experience an increase in our costs and expenses. In addition, as part of the payment processing process, we transmit our customers' credit card information to our third-party payment processor. We may in the future become subject to lawsuits or other proceedings for purportedly fraudulent transactions arising out of the actual or alleged theft of our customers' credit card information if the security of our third- party credit card payment processors are breached. We and our third- party credit card payment processors are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it difficult or impossible for us to comply. If we or our third- party credit card payment processors fail to comply with these rules or requirements, we may be subject to fines and higher transaction fees and lose our ability to accept credit card payments from our customers, and there may be an adverse impact on our business. 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 products, 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~~ **third- party sales agents and resellers** . 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. 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. In particular, 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 in a position 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 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. 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 a large accelerated filer** ~~Our term loan contains covenants that may restrict our business~~ and ~~financing activities. Our Loan~~ **may no longer provide scaled disclosures as a smaller reporting company beginning with our Quarterly Report on Form 10- Q for the quarter ending March 31, 2024, which will increase our costs** and **demands on management. We are a large accelerated filer and beginning with our Quarterly Report on Form 10- Q for the quarter ending March 31, 2024, we may no longer provide scaled disclosure as a " smaller reporting company " as defined under the** ~~Security~~ **Securities** ~~Agreement (~~ **Exchange Act of 1934,** as amended ~~,~~ **(** the **" Exchange Act "** ~~" Amended Loan Agreement")~~ ~~with Silicon Valley Bank~~ **. As a smaller reporting company, we had the option to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, as a non- accelerated filer and smaller reporting company, we have availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404 (b) of the Sarbanes Oxley Act** (" ~~SVB~~ **Section 404** ") ~~contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on SVB' s security interest over the collateral, a material adverse change, the occurrence of a default under certain other indebtedness incurred by us or our subsidiaries, the rendering of certain types of judgments against us and our subsidiaries, the revocation of certain government approvals, violation of covenants, and incorrectness of representations and warranties in any material respect~~ . **However** ~~The Amended Loan Agreement is secured by substantially all our assets other than our intellectual property. The Amended Loan Agreement includes affirmative and negative covenants applicable to us and certain of our foreign subsidiaries. The affirmative covenants include~~ , **we may no longer avail ourselves of this** ~~among others, covenants requiring us to maintain our legal existence and governmental compliance, deliver certain financial reports, and maintain~~

~~insurance coverage. The negative covenants include, among others, restrictions regarding transferring collateral, pledging our intellectual property to other parties, engaging in mergers or acquisitions, paying dividends or making other distributions, incurring indebtedness, transacting with affiliates, and entering into certain investments, in each case subject to certain exceptions~~ -- **exemption** ~~. The covenants in the Amended Loan Agreement,~~ as **a large accelerated filer, which** ~~well~~ **will increase** ~~as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in, expand, or~~ **our expenses** ~~otherwise pursue our business activities~~ and **require** ~~strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in~~ a **significant amount** ~~default under our credit facility agreements. If not waived, future defaults could cause all~~ of **management time** ~~the outstanding indebtedness under the Amended Loan Agreement to become immediately due and payable~~ . If we **fail** ~~do not have or are unable~~ to **maintain** ~~generate sufficient cash available to repay our debt obligations when they become due and~~ - **an effective system** ~~payable, either upon maturity or in the event~~ of ~~a default~~ **internal control over financial reporting** , we may not be able to **accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the market price of our common shares. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. We are also required to** obtain **an independent assessment of the effectiveness of our internal controls which could detect problems that our management' s assessment might not. Going forward, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses or significant deficiencies with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements, investors may lose confidence in our reported financial information, which could cause the market price of our common shares to decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require** additional ~~debt~~ **financial and management resources. Irrespective of compliance with Section 404, any failure of** ~~or~~ **our** ~~equity~~ **internal control over** ~~financing~~ **financial reporting could have a material adverse effect** on ~~favorable terms, if at all, which may negatively impact~~ our **stated** ~~ability to operate~~ **operating results and harm** our ~~business~~ **reputation** . Risks Related to Our Legal and Regulatory Environment We, our suppliers, and our third- party manufacturers are subject to extensive governmental regulation both in the **United States** ~~U. S~~ . 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~~ **authorities** . The FDA and other U. S. and foreign ~~governmental agencies~~ **regulatory authorities** 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 **and the issue of related CE Certificates of Conformity** ; • 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~~ **medical device** or make a significant modification to an existing product in the **United States** ~~U. S.~~ , with limited exceptions, we must obtain either clearance under Section 510 (k) of the FDCA for Class II devices or approval of a PMA 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, pre- clinical, 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 U. S., our currently commercialized products 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 expect, 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 investors that we will be able to obtain the 510 (k) clearances with respect to those products. **If current or future products that we seek to commercialize are determined to require a PMA or De Novo 510 (k) clearance, FDA may require evidence from clinical trials conducted under an investigational device exemption (" IDE "). Trials conducted under an IDE and a PMA or De Novo 510 (k) submission to the FDA can be lengthy and costly processes, which could delay and add to the cost of commercializing our products, which could adversely affect our financial results.** 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 products are safe and effective for their intended uses; • 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 products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any delay in, or failure to receive or maintain, clearance or approval for our products 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- marketing studies. 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 a 522 Order and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the **United States** ~~U. S.~~ In the ~~EEA~~ **EU** , ~~a single regulatory approval process exists, and conformity with its requirements is required to affix a CE mark to our medical devices, without which they~~ - **the** ~~cannot be marketed or sold in the EEA. To obtain a CE mark, defined products must meet minimum standards of performance, safety, and quality, and then, according to their classification, undergo a conformity assessment procedure. Except for low risk medical devices, a conformity assessment procedure requires the intervention of a third- party organization designated by the competent authorities of a EEA country, known as a Notified Body. The competent authorities of the E. U. countries separately regulate the clinical research for medical devices and the market surveillance of products once they are placed on the market. A new~~ Medical Device Regulation ~~was published by the E. U. in 2017 and~~ became ~~effective~~ **applicable** on May 26, 2021 **, repealing and replacing** ~~. Medical devices marketed in the EEA will require certification according to these~~ -- **the MDD. The** ~~new requirements, except that devices with valid CE certificates, issued pursuant to the~~ Medical Device **Regulation establishes transitional provisions** ~~Directives before May 2020, can be placed on the market until May 2024~~ . ~~The new~~ **However, the changes to the regulatory system implemented in the** EU ~~MDR~~ **by the Medical Device Regulation** ~~includes~~ - **include** ~~significant additional premarket~~ **stricter requirements for clinical evidence** and ~~post~~ **pre** - market **assessment of safety and performance, new classifications to indicate risk levels,** requirements ~~. Penalties~~ for ~~regulatory non-~~ **third party testing by Notified Bodies, tightened and streamlined QMS assessment procedures and additional requirements for the QMS, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfillment of the obligations imposed by the Medical Device Regulation may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body may consider that we have not adequately demonstrated** compliance **with** ~~could be severe, including fines and revocation or~~ **our** ~~suspension of related obligations to merit~~ a ~~company' s business license, mandatory price reductions and criminal sanctions~~ **CE Certificate of Conformity on the basis of the Medical Device Regulation** . The FDA and other regulatory authorities, including foreign authorities, have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some ~~surgeons~~ **physicians** from using our products and adversely affect our reputation and the perceived safety and effectiveness of our products. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: • warning letters; • fines; • injunctions; • civil penalties; • termination of distribution; • recalls or seizures of products; • delays in the introduction of products into the market; • total or partial suspension of production; • facility closures; • refusal of the FDA or our Notified Body or other regulator to grant future clearances or approvals or to issue CE Certificates of Conformity; • withdrawals, variation, or suspensions of current clearances or approvals and CE Certificates of Conformity, resulting in prohibitions on sales of our products; and • in the most serious cases, criminal penalties. Adverse action by an applicable regulatory ~~agency~~ **authority** , our Notified Body or the FDA could result in inability to produce our products 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 sales representatives must comply with U. S. federal and state fraud and abuse laws, including those relating to healthcare provider kickbacks and false claims for reimbursement, and other applicable federal and state healthcare laws, as well as equivalent foreign laws, and failure to comply could negatively affect our business. Healthcare providers, ~~distributors~~ **third- party sales agents and resellers** 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 third- party ~~distributors~~ **sales agents and resellers** 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 **coding of claims for reimbursement for medical procedures submitted to private and governmental payors and** reporting of **other** financial information or data, other commercial or regulatory laws or requirements, and equivalent foreign rules. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with 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 and our ~~distributors~~ **third- party sales agents and resellers** ' relationships with ~~surgeons~~ **physicians** , other healthcare professionals, and hospitals are subject to scrutiny under these laws. For example, we are subject to the federal health care Anti- Kickback Statute, the federal civil False Claims Act, the Health Insurance Portability and Accountability Act (" HIPAA ") and the federal Physician Payment Sunshine Act, each of which is described in detail in **"** Item 1 **.** Business- Healthcare Fraud and Abuse " and "- Data Privacy and Security Laws ". Certain states and countries also have enacted analogous state and foreign law equivalents of each of the above federal laws and may also mandate implementation of corporate compliance programs, require compliance with the industry' s voluntary compliance guidelines, impose restrictions on device manufacturer marketing practices, and / or require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities. Many of these state and foreign laws 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 subject to significant administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare, Medicaid, and equivalent foreign programs, significant fines, monetary penalties and damages, imposition of compliance obligations and monitoring, the curtailment or restructuring of our operations, and damage to our reputation. We have entered into consulting agreements and royalty agreements with physicians and healthcare executives, including some who are customers. We also engage in co- marketing arrangements with certain ~~surgeons~~ **physicians** who use our products. In addition, prior to our IPO, a small number of our current customer surgeons acquired from us less than 1. 0 % of our current outstanding common stock, 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 to comply with applicable laws, including the federal Anti- Kickback Statute, state anti- kickback laws and other applicable laws, 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 and criminal, civil and administrative liability. We would be materially and adversely affected if regulatory agencies interpret our financial relationships with ~~surgeons~~ **physicians** who order our products 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. Various state and federal regulatory and enforcement agencies **, and foreign equivalents,** continue actively to investigate violations of health care laws and regulations, and the U. S. Congress continues to strengthen the arsenal of enforcement tools. To enforce compliance with the federal laws, the U. S. Department of Justice has continued 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. **In addition, most of these laws apply to not only the actions taken by us, but also actions taken by our distributors and other third party agents, and healthcare providers with whom we interact. We have limited control over the business practices of our distributors and agents, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations, and financial condition.** 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, deferred or non- prosecution agreement, 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 and processes 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. **We are subject to stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security.** Our **actual or perceived** failure to **comply** ~~adequately protect personal information in compliance~~ with **such obligations** ~~evolving legal requirements~~ could **lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational** harm **; loss of revenue** ~~our~~ **or profits; loss of customers; and other adverse** business **consequences** . In the ordinary course of our business, we collect and ~~store~~ **process personal data and other** sensitive **information. We process** data **of our employees, consultants, certain individuals who may be affiliated with our customers** , including ~~legally protected~~ **physician users of our products and, in the context of clinical investigations, patients. The** ~~personally~~ -- **personal** ~~identifiable~~ **data may include sensitive personal data including health** information. We collect this kind of information for **several purposes, such as** billing, reimbursement support, marketing purposes, post- marketing safety vigilance, servicing potential warranty claims and during the course of

clinical trials. **We** ~~In doing so, we~~ are subject to various federal, state and foreign laws that protect the confidentiality of certain **sensitive information including** patient health information, ~~including~~ **such as** patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA in the **United States** ~~U. S.~~ and regulations in the European Union (" EU "), which are described in detail in **"** Item 1 **.** Business- Data Privacy and Security Laws **.** " **Many U. S. states have enacted laws regulating the collection, use and disclosure of personal data and requiring that companies implement reasonable data security measures. Laws in all states and U. S. territories also require businesses to notify affected individuals, governmental entities and / or credit reporting agencies of certain security breaches affecting personal data. These laws are not consistent, and increase our compliance costs and potential liability in the event of a data breach. In the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making** . The **exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the** California Consumer Privacy Act **of 2018** ~~, which became effective on January 1, 2020~~ , as amended by the California Privacy Rights Act **of 2020** (**" CPRA "), (collectively,** " CCPA ") **applies to personal data** ~~, requires a broad range~~ of **consumers,** ~~businesses~~ -- **business** ~~to honor the requests of~~ **representatives, and employees who are** California residents **,** ~~to access~~ and ~~require~~ **requires** ~~deletion~~ **businesses to provide specific disclosures in privacy notices and honor requests** of **such individuals to exercise** ~~their personal information, opt out of~~ certain **privacy rights** ~~personal information sharing, receive detailed information about how their personal information is used and shared, correct inaccurate personal information, and limit the use and disclosure of certain sensitive personal information~~ . The CCPA provides for **fines** ~~civil penalties~~ of up to $ 7, 500 ~~for~~ **per** intentional ~~violations~~ - **violation** ~~,~~ and ~~a~~ **allows** private ~~right of action for~~ **litigants affected by certain** data breaches ~~that allows private plaintiffs~~ to **recover significant** ~~seek the greater of actual damages or~~ statutory damages ~~of up to $ 750 per consumer per data breach. These remedies are expected to increase data breach litigation~~ . Although the CCPA includes exemptions for certain clinical trials data, and protected health information governed by HIPAA, the law may increase our compliance costs and potential liability with respect to other personal ~~information~~ **data** we collect about California residents. ~~Our~~ **Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and** compliance costs **for us, the third parties upon whom we rely, and our customers. Outside the United States,** ~~and~~ - **an** ~~potential liability with respect~~ **increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union' s General Data Protection Regulation (" GDPR ") and the United Kingdom' s GDPR (" UK GDPR ") impose strict requirements for processing personal data. The GDPR is directly applicable in each EU Member State. This should, in principle, result in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations requiring data controllers and processors** to **maintain a record of their data processing and policies. It requires data controllers to be transparent and to disclose to data subjects (in a concise, intelligible and easily accessible form) how their** personal information **is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i. e., key- coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non- compliance with the GDPR will be significant — the greater of € 20 million or 4 % of global turnover. The GDPR provides that EU Member States may introduce further conditions, including limitations, to the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. Each EU Member State** may also ~~increase~~ **adopt additional related legislation and guidance** in ~~response~~ **its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. We need** to **ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws. In the ordinary course of business, we may transfer personal data from Europe and** other **jurisdictions to the United** ~~states~~ **States** ~~adopting~~ **or other countries. Europe** and ~~considering initiative regarding protection~~ **other jurisdictions have enacted laws requiring data to be localized or limiting the transfer** of personal ~~information~~ **data to other countries** . In **particular** ~~March 2021~~ , ~~Virginia passed~~ the **European Economic Area** ~~Consumer Data Protection Act~~ (" ~~CDPA~~ **EEA** ") **and** ~~which will take effect on January 1, 2023. Virginia is~~ the **United Kingdom** ~~second state to pass comprehensive privacy litigation. Colorado passed the Colorado Privacy Act~~ (" ~~CPA~~ **UK** ") **have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely** on ~~July 7~~ **these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA** , ~~2021~~ **the UK or other jurisdictions to the United States, or if the**

requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with **partners** ~~enforcement to begin on July 1~~, ~~2023~~ **vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations** . In **addition to** ~~2022, both Utah and Connecticut also enacted comprehensive~~ data privacy **and security** ~~legislation. While these~~ laws **, we** are ~~similar~~ **contractually subject to industry standards adopted by industry groups and, we are, or may become subject to such obligations** in **the future. For example, we may also be subject to the Payment Card Industry Data Security Standard (" PCI DSS "). The PCI DSS requires companies to adopt** certain ~~respects~~ **measures to ensure the security of cardholder information** , **including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI- DSS can result in penalties ranging from $ 5, 000 to $ 100, 000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. We also rely on vendors to process payment card data, who may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance. We depend on a number of third parties in relation to the provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that** ~~the~~ **they only process personal data according to our instructions and applicable** laws ~~differ~~ **,** and **that they have sufficient technical and organizational security measures in place to fulfil their related obligations. These third party service providers may breach their contractual or legal obligations, which could negatively effect our business and / or our reputation. We publish privacy policies, marketing materials and other statements, such as** compliance with ~~one law does not equate to compliance with~~ **certain certifications or self- regulatory principles, regarding data privacy and security. If** ~~the~~ **these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or** other ~~laws~~ **adverse consequences** . ~~Several other states~~ **Obligations related to data privacy and security** (~~including Washington, New York,~~ and ~~Minnesota~~ **consumers' data privacy expectations**) ~~also~~ are **quickly changing, becoming increasingly stringent,** ~~considering comprehensive privacy legislation that could further complicate~~ and ~~increase~~ **creating uncertainty. Additionally,** ~~the~~ **these** ~~cost of~~ **obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and** complying with **these obligations requires us to devote significant resources** ~~various state privacy laws. If states pass a patchwork of privacy laws~~ , ~~this also could increase pressure~~ **which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data** on **our behalf. In addition,** ~~the~~ **these obligations may require us** ~~U. S. Congress~~ to **change our business model** ~~harmonize privacy laws through federal legislation~~ . We have in the past, and could be in the future, subject to data breaches. Our failure **(or perceived failure)** to comply with applicable ~~laws~~ **data privacy** and ~~regulations~~ **security obligations** , or to protect such data, could result in ~~enforcement actions against~~ **significant consequences to** 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 our operations, financial performance, and business. **In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.** Evolving and changing definitions of personal data ~~and personal information~~ , within the European Union, the **United States** ~~U. S.~~ , 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 products, 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 products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products. We are subject to risks associated with our non- U. S. operations. The FCPA prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. Other anti- corruption or anti- bribery laws, such as the UKBA, prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business in foreign countries. The FCPA also imposes accounting standards and requirements on publicly traded U. S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of slush funds from which such improper payments can be made. Because of the predominance of government- sponsored healthcare systems around the world, many of our customer relationships outside of the **United States** ~~U. S.~~ are with governmental entities and are therefore subject to such anti- bribery laws. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, and result in a material adverse effect on our business, results of operations, and financial condition. We also could suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures, including further changes or enhancements to our procedures, policies, and controls, as well as

potential personnel changes and disciplinary actions. Furthermore, we are subject to anti- boycott laws, anti- money laundering laws, and the export controls and economic embargo rules and regulations of the **United States** ~~U. S.~~, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute, or otherwise transfer our products or technology to prohibited countries or persons. A determination that we have failed to comply, whether knowingly or inadvertently, may result in substantial penalties, including fines and enforcement actions and civil and / or criminal sanctions, the disgorgement of profits, and the imposition of a court- appointed monitor, as well as the denial of export privileges, and may have an adverse effect on our reputation. Even if our products are approved by regulatory authorities or CE marked, if we, our contractors, or our suppliers fail to comply with ongoing FDA or other foreign regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market. For any product for which we obtain regulatory clearance or approval, or a CE Certificate of Conformity, 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, our Notified Body and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA' s Quality System Regulations (" QSR ") and **EU QMS requirements applicable to medical devices** ~~International Standards Organization (" ISO ") regulations~~ for the manufacture of our products 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, or a CE Certificate of Conformity. The failure by us or one of our suppliers 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 products; • operating restrictions or partial suspension or total shutdown of production; • refusing or delaying our requests for 510 (k) clearance or premarket approval and **applications for or conduct of** 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; • suspension, variation or withdrawal of CE Certificates of Conformity; • refusal to grant export approval for our products; and • criminal prosecution. In addition, we are required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR **or QMS** , 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 or CE Certificates of Conformity, 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. Any of these actions would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue.~~ Our employees, independent contractors, consultants, manufacturers, and third- party ~~distributors~~ **sales agents and resellers** 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, manufacturers, and third- party ~~distributors~~ **sales agents and resellers** may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct that violates applicable laws and regulations, such as FDA reporting requirements, manufacturing standards, federal, state and foreign healthcare laws and regulations, data privacy laws 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 which could result in regulatory sanctions and serious harm to our reputation. 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 products. Our promotional materials and training methods must comply with FDA and other applicable national and foreign laws and regulations, including the prohibition of the promotion of off- label use. Physicians may use our products off- label, as the FDA and equivalent third country authorities do not restrict or regulate a physician' s choice of treatment within the practice of

medicine. We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA and our ~~notified~~ **Notified** ~~body~~ **Body** . However, if the FDA or an equivalent ~~third country~~ **foreign regulatory** authority 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 products for those specific procedures until we obtain FDA or ~~third country~~ **foreign regulatory** authority 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 products would be impaired. Although our policy is to refrain from statements that could be considered off- label promotion of our products, the FDA or another regulatory ~~agency~~ **authority** could disagree and conclude that we have engaged in off- label promotion. In addition, the off- label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management' s attention, 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 products, which can result in voluntary corrective actions or agency enforcement actions. Under the FDA' s medical device reporting, regulations, and equivalent rules of other countries we are required to report to the FDA ~~or a similar~~ **and comparable foreign regulatory** ~~authority~~ **authorities** ~~in such other country~~ , 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. In the EEA, we must report serious incidents ~~and~~ **,** field safety corrective actions **and trend reports** through the **EUDAMED module** ~~Commission' s electronic system~~ on vigilance and post- market surveillance **. However** , ~~which~~ **EUDAMED is not yet fully functional and the related module on vigilance and post- market surveillance is not available yet. Until the entire EUDAMED system is fully functional, serious incidents and field safety corrective actions must be** ~~reports~~ **reported** ~~are transmitted~~ to the **national** competent ~~authority~~ **authorities through national systems** ~~of the Member State in which the incident occurred~~ . If we fail to report these events to the FDA or ~~applicable~~ **comparable foreign regulatory** ~~authority~~ **authorities** ~~in another country~~ within the required timeframes, or at all, FDA, or the ~~applicable~~ **competent foreign regulatory** authority ~~in the other country~~ could take enforcement action against us. Any such adverse event involving our products or repeated product malfunctions may result in voluntary or involuntary corrective actions, such as recalls or customer notifications, or ~~agency~~ action **by competent regulatory authorities** , 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 products 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 products, whether in the **United States** ~~U. S.~~ or abroad could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or ~~agency~~ action **by competent regulatory authorities** , 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 products, either voluntarily or at the direction of the FDA or another ~~governmental~~ **regulatory** authority, including foreign ~~governmental~~ **regulatory** authorities, or the discovery of serious safety issues or malfunctions with our products, can result in voluntary corrective actions or ~~agency~~ **regulatory** enforcement actions, which could have a significant adverse impact on us. The FDA and similar foreign ~~governmental~~ **regulatory** authorities have 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 products in the event of material deficiencies or defects in design or manufacture. A government- mandated or voluntary recall by us or one of our third- party ~~distributors~~ **sales agents or resellers** 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 products 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 products 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 have in the past, and may in the future, initiate voluntary recalls involving our products 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. Equivalent procedures and penalties have been established in other countries including EU Member States. Modifications to our products may require new 510 (k) clearances or premarket approvals and new conformity assessment by our Notified Body, or may require us to cease marketing or recall the modified products until clearances, approvals, or CE Certificates of Conformity are obtained. 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 to 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 some of our 510 (k) cleared products and have determined based on our review of the applicable FDA guidance that in certain instances new 510 (k) clearances or PMAs are 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. In these circumstances, we may be subject to significant enforcement actions, regulatory fines, or penalties, which could require us to redesign our products and harm our operating results. 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 products 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) program 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. In the EEA, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned **significant changes are made to the products or if there are** substantial changes to our quality **assurance** ~~system~~ **systems** ~~, manufacturing process, or changes to our devices which could affect~~ **affecting** ~~compliance with the~~ **those products** ~~essential requirements or the devices' intended use~~ . The Notified Body will then assess the changes and ~~verify~~ **determine** whether ~~they affect~~ **additional audits or actions are required prior to** ~~the~~ **their** ~~products'~~ **implementation. Obtaining variation of existing CE Certificates of** ~~conformity~~ **Conformity or a new CE Certificate of Conformity** ~~with Essential Requirements and related applicable laws. There~~ can be **a time- consuming process,** ~~no assurances that the assessment will be favorable~~ and ~~that the Notified Body will attest to~~ **delays in obtaining required future clearances, certifications** ~~our~~ **or** ~~compliance with the essential requirements~~ **approvals would adversely affect our ability to introduce new or enhanced products in a timely manner** , which ~~will prevent us from selling our products~~ in ~~the EEA~~ **turn would harm our future growth** . Moreover, any substantial changes that take place in the coming years may impact the continuing ~~effectiveness~~ **validity** of our CE Certificates of Conformity that were issued on the basis of the Medical Device Directive. There is no guarantee that the FDA will grant 510 (k) clearance or premarket approval of our future products or that our Notified Body will issue the required CE Certificate of Conformity, and failure to obtain necessary clearances or approvals for our future products would adversely affect our business prospects. We are in the process of developing our regulatory strategies for obtaining clearance ~~or~~ approval **or CE Certificates of Conformity** for future products. Some of them may require 510 (k) clearance by the FDA or a new CE Certificate of Conformity **by a Notified Body** . Other future products may require premarket approval. In addition, some of our new products may require clinical trials or significant clinical evidence to support regulatory approval and we may not successfully complete these clinical trials. Obtaining regulatory clearances or approvals and CE Certificates of Conformity can be a time- consuming process, and delays in obtaining required future regulatory clearances or approvals, and CE Certificates of Conformity would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would adversely affect our business prospects. The FDA may not approve or clear these products or our Notified Body may not issue CE Certificate of Conformity for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510 (k) clearance or premarket approval of new products, new intended uses, or modifications to existing products and our Notified Body may refuse to issue new CE Certificates of Conformity. Failure to receive clearance, approval, or **CE** Certificates of Conformity for our new products would have an adverse effect on our ability to expand our business. We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries. We currently market our products internationally and intend to expand our international marketing. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. For example, we intend to continue to seek domestic and international regulatory clearance to market our primary products Asia, the Middle East and other key markets. The approval procedures vary among countries and may involve requirements for substantial additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain FDA clearance or approval or to obtain CE Certificates of Conformity. Clearance or approval by the FDA or obtaining a CE Certificate of Conformity does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval, or a CE Certificate of Conformity for a medical device in the EEA, in addition to other risks. In addition, the time required to obtain foreign approval may differ from that required to obtain FDA clearance or approval, or a CE Certificate of Conformity in the EEA, and we may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, results of operations, and financial condition could be adversely affected ~~. Clinical trials necessary to support a De Novo 510 (k) or PMA application or a conformity assessment procedure will be expensive and 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 will prevent us from commercializing any modified or new products, or new indications for use for existing products, and will adversely affect our business, operating results and prospects. Initiating and completing clinical trials necessary to support a De Novo 510 (k) or PMA application for our possible future products or to support a conformity assessment procedure for a new CE Certificate of Conformity would be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product, or new indication for use, we advance into clinical trials may not have favorable results in later clinical trials. Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow- up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity of patients to clinical sites, and the ability to comply with the inclusion and exclusion criteria for participation in the clinical trial and patient compliance. Development of sufficient and appropriate clinical protocols to demonstrate safety and effectiveness are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA or our Notified Body may require us to submit data on a greater number of patients than we originally anticipated and / or for a longer follow- up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. For example, the COVID- 19 pandemic caused substantial delays in site initiation and patient enrollment in our SILVIA trial designed to assess the safety and efficacy of our Bedrock technique. In addition, despite considerable time and expense invested in our clinical trials, the FDA or our Notified Body may not consider our data adequate to demonstrate safety and effectiveness. Such increased costs and delays or failures could adversely affect our business, operating results and prospects. Our facility and our clinical investigational sites operate under procedures that govern the conduct and management of FDA- regulated clinical studies under 21 CFR Parts 50 and 812, and Good Clinical Practices. The FDA may conduct Bioresearch Monitoring inspections of us and / or our clinical sites to assess compliance with 21 CFR Parts 50 and 812, our procedures, and the clinical protocol. If the FDA were to find that we or our clinical investigators are not operating in compliance with applicable regulations, we could be subject to the above FDA enforcement action, as well as refusal to accept all or part of our data in support of our 510 (k) or PMA, or we may need to conduct additional studies~~ . The results of our clinical trials may not support our product candidate claims or may result in the occurrence of adverse events. Even if our clinical trials are completed as planned, or on a delayed basis, we cannot be certain that their results will support our product candidate claims or that the FDA, foreign authorities, or our Notified Body will agree with our conclusions regarding them. Success in pre- clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre- clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenue. It is also possible that patients enrolled in clinical trials will experience adverse events that are not currently part of the product candidate' s profile. U. S. legislative or FDA or foreign regulatory reforms may make it more difficult and costly for us to obtain regulatory clearances or approvals, or CE Certificates of Conformity for our product candidates and to manufacture, market, and distribute our products after approval is obtained. From time to time, Congress introduces legislation that could significantly change the statutory provisions governing the regulatory approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. ~~Moreover, the new Medical Device Regulation entered into application on May 26, 2021.~~ Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be. Leadership, personnel and structural changes within the FDA as well as recent federal election outcomes could result in significant legislative and regulatory reforms impacting the FDA' s regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. Another example can be found in the EEA. The Medical ~~Devices~~ **Device** Regulation ~~(" MDR ")~~ entered into application on May 26, 2021 ~~. MDR~~ **, and** introduced substantial changes to the obligations with which medical device manufacturers must comply in the EEA. Examples of the changes ~~which will be~~ introduced by ~~these~~ -- **the Medical Device** ~~regulations~~ **Regulations** include the following: • additional scrutiny during the conformity assessment procedure for high risk medical devices; • strengthening of the clinical data requirements related to medical devices; • strengthening of the designation and monitoring processes governing ~~notified~~ **Notified** ~~bodies~~ **Bodies** ; • the obligation for manufacturers and authorized representative to have a person responsible for regulatory compliance continuously at their disposal; • authorized representatives held legally responsible and liable for defective products placed on the EU market; • increased traceability of medical devices following the introduction of a Unique Device Identification (" UDI "), system; • new rules governing the reprocessing of medical devices; and • increased transparency with the establishment of European database on medical devices (" EUDAMED ") III as information from several databases concerning economic operators, CE Certificates of Conformity, conformity assessment, clinical investigations, the UDI system, adverse event reporting and market surveillance would be available to the public. The Medical Device Regulation

also substantially impacts clinical investigations of medical devices. Among other things, it imposes specific obligations concerning incapacitated subjects, minors, pregnant or breastfeeding women and clinical investigations in emergency situations. In addition to detailed provisions concerning the authorization and conduct of clinical investigations, the Regulation imposes on non- EU sponsors a responsibility to appoint a legal representative established in the EU and an obligation on EU Member States to ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place and places on sponsors and investigators the obligation to ensure they make use of these systems. Transition **of our products** from the ~~regulation~~ **regulatory framework** of ~~our products under~~ the **MDD** ~~Medical Device Directive, and implementing legislation in each EU Member State,~~ to **the** ~~regulation~~ **regulatory** ~~under~~ **framework of** the Medical Devices Regulation has required and will continue to require a substantial transition effort by us. In ~~addition~~ **the EU** , ~~detail~~ **Notified Bodies must be officially designated by a Competent Authority of an EEA country. While several Notified Bodies have been designated, the currently designated Notified Bodies are facing a large amount of requests for (re) certification under the MDR and** as **a consequence, review times have lengthened** ~~to how certain aspects of the Medical Devices Regulation will be applied remains unclear~~ . **Furthermore,** ~~Failure~~ **failure** to update our quality system and regulatory documentation could delay our ~~transition to~~ compliance with the Medical Devices Regulation and delay or prevent us from obtaining new CE Certificates of Conformity **issued in accordance** ~~under the Regulation. Transition from compliance~~ with the Medical Device ~~Directive~~ **Regulation. Transition** to the Medical Devices Regulation could result in disruption to our business in the EEA which could adversely affect our business, results of operation and financial condition. In addition, any changes to the membership of the European Union, such as the departure of the United Kingdom from the EU, may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries. For example, **the exit of** ~~pursuant to guidance issued by~~ the UK ~~Government~~ **from the EU, commonly referred to** as ~~a result of~~ **" Brexit " could lead to regulatory divergence between the EU and** the UK **. On May 26** ~~formally withdrawing from the European Union~~ , **2021,** the **Medical Device** ~~Medicines and Healthcare products Regulatory~~ **Regulation** ~~Agency (" MHRA ")~~ became **applicable in** the ~~standalone medicines and~~ **EU. However, the Medical Device Regulation is not applicable in the UK. In the UK,** medical devices ~~regulator for~~ **are governed by** the ~~UK~~ **Medical Devices Regulations 2002 (SI 2002 No 618,** as **amended)** ~~of January 1, 2021. A new mark referred to as " UKCA "~~ (UK ~~Conformity Assessed~~ **MDR 2002**) **which, for** ~~has also been introduced and will replace~~ the ~~CE conformity mark. Although CE conformity marketing and certificates issued~~ **time being, retains a regulatory framework similar to the framework set out** by ~~Notified Bodies will continue to be recognized in~~ the **MDD. The** UK ~~through June 2023, all~~ **government plans to introduce new legislation governing** medical devices ~~must be registered~~ with ~~the MHRA as~~ **an aim for core aspects** of ~~January~~ **the future regime for medical devices to apply from July** 1, ~~2021~~ **2025** . ~~Complying with this new~~ **New legislation has been proposed and is also anticipated for adoption in 2024 to bring into force strengthened post- market surveillance requirements ahead of the wider future** regulatory ~~framework will require us~~ **regime. These post- market surveillance requirements are expected** to ~~invest in additional resources and~~ **apply from mid- 2024. Should the UK or Great Britain further diverge from the EU from a regulatory perspective, tariffs** could be **put into place in the future. We could therefore, both now and in the future, face significant additional** ~~expensive~~ **expenses to operate our business , which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import / export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the UK. Moreover, in the EU, some EU Member States may, after a medical device is CE marked, require the completion of additional studies that compare the cost- effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021 / 2282 on HTA, amending Directive 2011 / 24 / EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies and providing the basis for cooperation at EU level for joint clinical assessments in these areas. If the conclusions of these assessments are negative, or compare our products unfavorably with competing products, this may impact our pricing and reimbursement status. If we are unable to obtain or maintain favorable pricing and reimbursement status in EU Member States for our medical devices or medical devices that we may successfully develop and for which we may obtain certification, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. Inadequate funding for the FDA and other government agencies, or a work slowdown or stoppage at those agencies as part of a broader federal government shutdown, or comparable scenarios with foreign regulatory authorities, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve or clear new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA' s ability to perform routine functions. Disruptions at FDA and other agencies may also slow the** time ~~consuming and disruptive~~ **necessary for new product applications** to **be reviewed and /** ~~our~~ **or** ~~existing~~ **approved by**

necessary government agencies, which could adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U. S. government shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. Average review times at FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations ~~in~~ **may rely is subject to the political process, which is inherently fluid and unpredictable. If a prolonged government shutdown occurs, or if global health concerns or ~~the~~ other ~~UK~~ political or world events prevent the FDA or other regulatory authorities from conducting their regular reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns or delays could also impact our ability to access the public markets and obtain capital to fund the growth of our operations. Similar considerations and concerns apply to foreign regulatory authorities** . 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 surgical devices. Sacroiliac joint and other orthopedic spine surgeries involve significant risk of serious complications, including bleeding, nerve injury, paralysis, and even death. ~~Surgeons or non- surgeon physicians~~ **Physicians** may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. In addition, if longer- term patient results and experience indicate that our products or any component of a product cause tissue damage, motor impairment, or other adverse effects, we could be subject to significant liability. 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. The manufacture of certain of our products, including our implants and products, and the handling of materials used in the product testing process involve the use of biological, hazardous and / or radioactive materials and wastes. Our business and facilities and those of our suppliers are subject to foreign, federal, state, and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling, and disposal of, and exposure to, such materials and wastes. We own and operate certain x- ray equipment at our facilities which requires adoption of a radiation safety plan. Our failure to follow such safety plan or otherwise use this equipment properly could be hazardous to our employees and expose us to liability as the employer. 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. Certain of our products are derived from human tissue and are or could be subject to additional regulations and requirements. Our iFuse Bone product is derived from human bone tissue, and as a result is subject to FDA and certain state regulations regarding human cells, tissues and cellular or tissue- based products, or HCT / Ps. To date, iFuse Bone is our only HCT / P product, and as a product regulated under Section 361 of the Public Health Service Act, we have not been required to file a 510 (k) with respect to iFuse Bone. However, the FDA could require us to obtain a 510 (k) clearance for future tissue products not regulated as 361 HCT / Ps. The process of obtaining a 510 (k) clearance could take time and consume resources, and failing to receive such a clearance would render us unable to market and sell such products, which could have a material and adverse effect on our business. **In addition, procurement of certain human organs and tissue for transplantation is subject to the National Organ Transplant Act (" NOTA"), which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment for costs associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage, and transportation of donated human tissue they provide to use for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control, and storage of the tissue, marketing and medical education expenses, and costs associated with development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses we can recover in our pricing for our products, thereby reducing our future revenue and profitability. If we were to be found to have violated NOTA' s prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations.** Risks Related to Our Intellectual Property If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired. We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and nondisclosure agreements and other methods, to protect our proprietary technologies and know- how. As

of December 31, ~~2022~~ **2023**, we owned ~~51~~ **59** issued U. S. patents and had ~~32~~ **34** pending U. S. patent applications, and we owned ~~16~~ **18** issued foreign patents and had ~~18~~ **22** pending foreign patent applications. We have focused the majority of our foreign patent efforts in China, Europe, and Japan. Our current U. S. patents on iFuse, including the triangular shape, expire in ~~November~~ **December** ~~2024~~ **2025**. Competitors may market similar triangular shaped devices upon the expiration of the patents in late ~~2024~~ **2025**. Our current U. S. patents on iFuse- 3D, including the fenestrated design, expire in September 2035. Our foreign patents will expire between August 2025 and September 2035. As of December 31, ~~2022~~ **2023**, we have ~~19~~ **20** registered trademarks in the **United States** ~~U. S.~~ and have filed for ~~four~~ **three** more. We have sought protection for at least two of these trademarks in ~~60~~ **61** countries including the 27 European member countries of the Madrid Protocol. 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 our products, we may not accurately predict all of 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 at a later date. Furthermore, we cannot assure investors 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 that 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** ~~U. S.~~ Even if patents are granted outside the **United States** ~~U. S.~~, effective enforcement in those countries may not be available. Since most of our issued patents are for the **United States** ~~U. S.~~ 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 products. We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. We cannot assure investors 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 products, 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 investors 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, 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 our third- party ~~distributors~~ **sales agents or resellers** 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 of our third- party ~~distributors~~ **sales agents or resellers** sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees, or our third- party ~~distributors~~ **sales agents or resellers** 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 occur, 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** ~~U. S.~~ 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 products. 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 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 products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, 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. In addition, we generally indemnify our customers and third- party ~~distributors~~ **sales agents and resellers** with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or third- party ~~distributors~~ **sales agents and resellers** . These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or third- party ~~distributors~~ **sales agents and resellers** , regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or third- party ~~distributors~~ **sales agents and resellers** or may be required to obtain licenses to intellectual property owned by such third parties. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers and third- party ~~distributors~~ **sales agents and resellers** may be forced to stop using or selling our products. Risks Related to Ownership of Our Common Stock The price of our common stock may be volatile, and the value of an investment in our common stock could decline. Medical device stocks have historically experienced volatility, and the trading price of our common stock may fluctuate substantially. These fluctuations could cause our stockholders to lose all or part of their investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include the following: • changes in interest rates, investor risk appetite and other macroeconomic factors impacting the market for securities issued by medical device companies; • the risk of inflation, interest rate increases and other macroeconomic factors impacting patients' economic ability and likelihood of undergoing elective procedures, whether real or as perceived by investors; • actual or anticipated changes or fluctuations in our results of operations; • the impact of **infectious diseases, and measures taken to combat** ~~the~~ **them ,** ~~COVID- 19 pandemic~~ on our business; • results of our clinical trials and that of our competitors' products; • regulatory actions with respect to our products or our competitor' s products; • announcements of new offerings, products, services or technologies, commercial relationships, acquisitions, or other events by us or our competitors; • price and volume fluctuations in the overall stock market from time to time; • significant volatility in the market price and trading volume of healthcare companies, in general, and of companies in the medical device industry in particular; • fluctuations in the trading volume of our shares or the size of our public float; • negative publicity; • whether our results of operations meet the expectations of securities analysts or investors or those expectations change; • litigation involving us, our industry, or both; • regulatory developments in the **United States** ~~U. S.~~ , foreign countries, or both; • lock- up releases and sales of large blocks of our common stock; • additions or departures of key employees or scientific personnel; and • general economic conditions and trends. In addition, if the market for healthcare stocks or the stock market, in general, experience a further 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. Our sales volumes and our operating results may fluctuate over the course of the year, which could affect the price of our common stock. We have experienced and continue to experience meaningful variability in our sales and gross profit from quarter to quarter, as well as within each quarter. Our sales and results of operations will be affected by numerous factors, including, among other things: • payor coverage and reimbursement; • the number of products sold in the quarter and our ability to drive increased sales of our products; • our ability to establish and maintain an effective and dedicated sales force; • pricing pressure applicable to our products, including adverse third- party coverage and reimbursement

outcomes; • the impact of ~~the~~ COVID- 19 ~~pandemic~~ or other ~~epidemic~~ **infectious** disease ~~outbreak~~ **outbreaks** on our business; • results of clinical research and trials on our existing products and products in development; • the mix of our products sold because profit margins differ amongst our products; • timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; • the ability of our suppliers to timely provide us with an adequate supply of materials and components; • the evolving product offerings of our competitors; • the demand for, and pricing of, our products and the products of our competitors; • factors that may affect the sale of our products, including seasonality and budgets of our customers; • domestic and international regulatory clearances or approvals, or CE Certificates of Conformity, and legislative changes affecting the products we may offer or those of our competitors; • interruption in the manufacturing or distribution of our products; • 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; • the number of selling days in the quarter; • fluctuation in foreign currency exchange rates; 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** ~~U. S.~~, and commercialization of such products outside of the **United States** ~~U. S.~~ would likely require additional regulatory approvals, or Certificates of Conformity and import licenses. 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 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. We may be unable to utilize our federal and state net operating loss carryforwards to reduce our income taxes. As of December 31, ~~2022~~ **2023**, we had net operating loss (" NOL ") carryforwards of $ ~~298~~ **331**. 6 million and $ ~~238~~ **259**. ~~7~~ **6** million available to reduce future taxable income, if any, for U. S. federal income tax and state income tax purposes, respectively. If not utilized, our federal and state NOL carryforwards begin to expire in **2030 and** ~~2029~~ **2023** ~~and 2022~~, respectively, subject to the recent California franchise tax law change affecting California state NOLs mentioned below. Portions of these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under legislation enacted in 2017, as modified by legislation enacted in 2020, unused U. S. federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020, is limited to 80 % of taxable income. At the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which generally occurs if the percentage of the corporation' s stock owned by 5 % stockholders increases by more than 50 % over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income may be limited. We updated our Section 382 ownership change analysis through December 31, 2020. The analysis determined that we have experienced Section 382 ownership changes in 2010 and 2020. A total of $ 1. 4 million of our NOLs and tax credit carryforwards are subject to limitation as a result of the ownership change. ~~The California Assembly Bill 85 (AB 85) was signed into law by Governor Gavin Newsom on June 29, 2020. The legislation suspends the California NOL deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation of certain California Tax Credits for 2020, 2021, and 2022. The legislation disallows the use of California NOL deductions if the taxpayer recognizes business income and its adjusted gross income is greater than $ 1. 0 million. The carryover periods for NOL deductions disallowed by this provision will be extended. On February 9, 2022, California Senate Bill 133 (SB 133) was signed into law. The new bill lifted the limitation for California NOL and credit utilization disallowed by AB 85. We will continue to monitor the possible California NOLs and credit limitation in future periods.~~ Our charter documents and Delaware law could discourage takeover attempts and lead to management entrenchment. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions include: • a classified board of directors with three- year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors; • the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror; • the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors, or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; • the requirement for the affirmative vote of holders of at least 66 2 / 3 % of the voting power of all of the then- outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and • advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of us. In addition,

as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of, and do not currently intend to opt out of, this provision. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U. S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which restricts our stockholders' ability to bring a lawsuit against us or our directors, officers, or employees in jurisdictions other than Delaware and federal district courts. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for these types of disputes with us or our directors, officers, or other employees. Our amended and restated certificate of incorporation also provides that the U. S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. **Adverse developments affecting the banking industry or the broader financial services industry, such as actual events or concerns involving liquidity, defaults or non- performance, could adversely affect our operations and liquidity. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB"), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC"), as receiver. Although a statement by the U. S. Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day following the date of closure and we and other depositors with SVB received such access on March 13, 2023, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all. Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity. In addition, if any parties with whom we conduct business are unable to access funds held in uninsured deposit accounts or pursuant to lending arrangements with a financial institution that is placed in receivership by the FDIC, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Our loan and security agreement contains covenants that may restrict our business and financing activities. Our Loan and Security Agreement (as amended, the" Amended Loan Agreement") with First-Citizens Bank & Trust Company (" First- Citizens ") contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on First- Citizens security interest over the collateral, a material adverse change, the occurrence of a default under certain other indebtedness incurred by us or our subsidiaries, the rendering of certain types of judgments against us and our subsidiaries, the revocation of certain government approvals, violation of covenants, and incorrectness of representations and warranties in any material respect. The Amended Loan Agreement is secured by substantially all our assets other than our intellectual property, which intellectual property is subject to a negative pledge under the terms of the Amended Loan Agreement. The Amended Loan Agreement includes affirmative and negative covenants applicable to us and certain of our foreign subsidiaries. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental compliance, deliver certain financial reports, and maintain insurance coverage. The negative covenants include, among others, restrictions regarding transferring collateral, pledging our intellectual property to**

other parties, engaging in mergers or acquisitions, paying dividends or making other distributions, incurring indebtedness, transacting with affiliates, and entering into certain investments, in each case subject to certain exceptions. The covenants in the Amended Loan Agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in, expand, or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under our credit facility agreements. If not waived, future defaults could cause all of the outstanding indebtedness under the Amended Loan Agreement to become immediately due and payable. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate our business. Our ability to access credit on favorable terms, if necessary, for the funding of our operations and capital projects may be limited due to changes in credit markets. Our Amended Loan Agreement with First- Citizens provides for a secured revolving credit facility (the " Revolving Line "), in an aggregate principal amount of up to $ 15. 0 million. The Revolving Line matures on July 6, 2025. As of December 31, 2023, we had not drawn on this credit facility. On March 10, 2023, we violated certain terms of the Amended Loan Agreement by opening bank accounts with another financial institution and transferring funds from SVB. We entered into a letter agreement with Silicon Valley Bridge Bank waiving enforcement of this covenant and providing us the right to hold a portion of our cash at other financial institutions. Any future violation of any of the covenants, as amended, could result in a default under the Amended Loan Agreement that would permit First- Citizens to restrict our ability to further access the Revolving Line for loans and require the immediate repayment of any outstanding loans under the agreement. In addition, certain provisions in the these covenants are subject to renegotiation at the beginning of each fiscal year, which further reduces our ability to anticipate whether this source of capital will continue to be available in the near term. As of December 31, 2023, we had cash management accounts with a financial institution other than First- Citizens and instructed our customers to direct payments to us to these separate operating accounts. Until certain such customer payments to third party operating accounts are re- directed to the cash collateral accounts with First- Citizens, and certain account balances are moved back to cash collateral accounts and other accounts held at First- Citizens, we will be unable to obtain credit advances under the Revolving Line. See " Note 7. Borrowings " to the " Notes to Consolidated Financial Statements " included in this report. Additionally, in the past, the credit markets and the financial services industry have experienced disruption characterized by the bankruptcy, failure, collapse or sale of various financial institutions, increased volatility in securities prices, diminished liquidity and credit availability and intervention from the U. S. and other governments. Continued concerns about the systemic impact of potential long- term or widespread downturn, energy costs, geopolitical issues, the availability and cost of credit, the global commercial and residential real estate markets and related mortgage markets and reduced consumer confidence have contributed to increased market volatility. The cost and availability of credit has been and may continue to be adversely affected by these conditions. We cannot be certain that funding for our capital needs will be available from our existing financial institutions and the credit markets if needed, and if available, to the extent required and on acceptable terms. The Amended Loan Agreement terminates on December 1, 2027, and if we cannot renew or refinance this facility or obtain funding when needed, in each case on acceptable terms, such conditions may have an adverse effect on our ability to operate our business.