Risk Factors Comparison 2024-02-29 to 2023-03-02 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10- K, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10- K, before deciding whether to invest in shares of our common stock. The risks described below are not the only ones we face. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and future prospects. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. Please also see the section titled " Special Note Regarding Forward- Looking Statements." Risks Related to Our Financial Condition and Capital Requirements If we..... our business. Risks Related to Our Business and Industry Our business plan relies on certain assumptions..... financial condition and results of operations. Our business is dependent upon the broad adoption of our products by hospitals, physicians and patients. Our future growth and profitability depend on our ability to increase physician and patient awareness of our products and on the willingness of physicians and hospitals to adopt our products. Physicians may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products provide a safe and effective treatment for foot and ankle conditions. Even if we are able to raise awareness among physicians, they may be slow in changing their medical treatment practices and may be hesitant to select our products for a variety of reasons, including: • lack of experience with our products and concerns that we are relatively new to market; • long- standing relationships with companies and distributors that sell other products; • lack of availability of adequate third- party payor coverage or reimbursement; • competitive response and negative selling efforts from providers of alternative treatments; • perception regarding the time commitment and skill development that may be required to gain familiarity and proficiency with our products; • perceived liability risk generally associated with the use of new products and treatment options; • lack or perceived lack of sufficient clinical evidence, including long- term data, supporting clinical benefits or the cost- effectiveness of our products over existing treatments; and • the failure of key opinion leaders to provide recommendations regarding our products, or to assure physicians, patients and healthcare payors of the benefits of our products as an attractive alternative to other treatment options. To effectively market and sell our products, we will need to continue to educate the medical community about the safety, efficacy, necessity and efficiency of our products and about the patient population that would potentially benefit from using our products. We cannot assure you that we will achieve broad education or market acceptance among physicians. In addition, some physicians may choose to utilize our products on only a subset of their total patient population or may not adopt our products at all. If we are not able to effectively demonstrate that our products are beneficial for a broad range of patients, adoption of our products will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that our products will achieve broad market acceptance among hospitals, physicians and patients. Any failure of our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations . We operate in a very competitive..... time to recover over the winter holidays . Our long- term growth depends on our ability to enhance our products, expand our indications and develop and commercialize additional products in a timely manner. If we cannot innovate, we may not be able to develop or exploit new products in time to remain competitive. The market for our products is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. For us to remain competitive, it is essential to develop and bring to market new products. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products. Developing products is expensive and time-consuming and could divert management' s attention away from our core business. The success of any new product offering or product enhancements to our solution will depend on several factors, including our ability to: • assemble sufficient resources to acquire or discover additional products; • properly identify and anticipate surgeon and patient needs; • develop and introduce new products and product enhancements in a timely manner; • avoid infringing upon the intellectual property rights of third-parties; • demonstrate, if required, the safety and efficacy of new products with data from preclinical and clinical studies and clinical trials; • obtain the necessary regulatory clearances, approvals or certifications for expanded indications, new products or product modifications; • be fully compliant with U. S. Food and Drug Administration (FDA) regulations and be fully compliant with foreign regulations marketing of new devices or modified products; • produce new products in commercial quantities at an acceptable cost; • provide adequate training to potential users of our products; • receive adequate coverage and reimbursement for procedures performed with our products; and • develop an effective and dedicated sales and marketing team. If we are unable to develop or improve products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors have the capability to devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that could allocate greater resources to research and

development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business. In addition, we may choose to focus our efforts and resources on potential products or indications that ultimately prove to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential products or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential products through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights, which could adversely impact our business, financial condition and results of operations ~~and procedures.However,the projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize,or if non- surgical treatments or other surgical techniques gain more widespread acceptance as a viable alternative to our foot and ankle solutions and procedures.In addition,even if the number of patients suffering from foot and ankle disorders who elect to undergo surgery increases as we expect,technological or medical advances could provide alternatives to address foot and ankle disorders and reduce demand for foot and ankle surgery.As a result,our estimates of the addressable market for our current or future products and procedures may prove to be incorrect.Even if the total addressable market for our current and future products and procedures is as large as we have estimated,we may not be able to penetrate the existing market to capture additional market share for the reasons discussed in this " Risk Factors " section.If the actual number of patients suffering from foot and ankle disorders who would benefit from our products,the price at which we can sell future products or the addressable market for our products is smaller than we estimate,or if the total addressable market is as large as we have estimated but we are unable to capture additional market share,it could have a material adverse effect on our business,financial condition and results of operations~~ .We operate in a very competitive business environment,and if we are unable to compete successfully against our existing or potential competitors,our business,financial condition and results of operations may be adversely affected.Our existing foot and ankle products and procedures are,and any new foot and ankle products or procedures we develop and commercialize will be,subject to intense competition.The industry in which we operate is competitive,subject to change and sensitive to the introduction of new products,procedures or other market activities of industry participants.Our ability to compete successfully will depend on our ability to continue to promote awareness,educate and train foot and ankle specialists with our foot and ankle products and procedures and gain their acceptance;develop additional products and procedures to improve our foot and ankle offerings and expand our product offerings in a timely manner;receive adequate coverage and reimbursement from third- party payors;and provide products that are easier to use,safer,less invasive and more effective than the products and procedures of our competitors.In addition,our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing efforts.We plan to dedicate significant resources to our marketing programs.It will negatively affect our business,financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue.In addition,we believe that developing and maintaining broad awareness of our products in a cost- effective manner is critical to achieving broad acceptance of our products and expanding domestically and internationally.Promotion activities may not generate patient or physician awareness or increase revenue,and even if they do,any increase in revenue may not offset the costs and expenses we incur in building our brand.If we fail to successfully promote,maintain and protect our brand,we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts,or to achieve the level of brand awareness that is critical for broad adoption of our products.In the foot and ankle market,we compete with large multinational companies such as Stryker,Arthrex,Smith & Nephew,J & J and Zimmer Biomet as well as with companies with one or a limited number of foot and ankle products such as Enovis,CrossRoads,Medline,Conmed, **Novastep** and Treace.We also face potential competition from many different sources,including academic institutions,governmental agencies and public and private research institutions.At any time,these competitors and other potential market entrants may develop new products,procedures or treatment alternatives that could render our products obsolete or uncompetitive.In addition,one or more of such competitors may gain a market advantage by developing and patenting competitive products,procedures or treatment alternatives earlier than we can,obtaining regulatory clearances,approvals or certifications more rapidly than we can or selling competitive products at prices lower than ours.If medical research were to lead to the discovery of alternative therapies or technologies that improve or cure certain foot and ankle maladies as an alternative to surgery,such as by natural correction of the unstable joint in the middle of the foot,the use of pharmaceuticals or breakthrough bio- technological innovations or therapies,our profitability could suffer through a reduction in sales or a loss in market share to a competitor.The discovery of methods of prevention or the development of other alternatives to address certain foot and ankle maladies that we treat could result in decreased demand for our products and,accordingly,could have a material adverse effect on our business,financial condition and results of **operations.Many of our current and potential competitors have substantially greater sales and financial resources than we do,more established distribution networks,a broader offering of products,entrenched relationships with surgeons and distributors and greater experience in launching,marketing,distributing and selling products or treatment alternatives.We also compete with our competitors to engage the services of independent sales representatives,both those presently working with us and those with whom we hope to work with as we expand.In addition,we compete with our competitors in acquiring technologies and technology licenses complementary to our products or procedures or advantageous to our business.If we are unable to compete successfully against our existing or potential competitors,our business,financial condition and results of operations may be adversely affected,and we may not be able to grow at our expected rate,if at all.The seasonality of our business creates variance in our quarterly revenue,which makes it difficult to compare or forecast our financial results.Our revenue fluctuates on a seasonal basis,which affects the comparability of our results between periods.In particular,we have experienced and expect to**

continue to experience seasonality in our business,with higher U.S.sales volumes in the fourth calendar quarter.Our U.S.sales volumes in the fourth calendar quarter tend to be higher as many patients elect to have surgery after meeting their annual deductible and having time to recover over the winter holidays . We may expend our limited resources to pursue a particular product or indication and fail to capitalize on product or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs and products that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other products or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and products for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product, we may relinquish valuable rights to that product through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product. We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance. Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA or approved or certified in foreign jurisdictions and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future enhancements to our products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we may face product liability suits. We may be subject to product liability claims if our products cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: • costs of litigation; • distraction of management' s attention from our primary business; • the inability to commercialize our products and develop enhancements to our products; • decreased demand for our products; • damage to our business reputation; • product recalls or withdrawals from the market; • withdrawal of clinical trial participants; • substantial monetary awards to patients or other claimants; or • loss of sales. Additionally, we could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations. Although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Further, such product liability matters may negatively impact our ability to obtain insurance coverage or cost- effective insurance coverage in future periods. Industry trends have resulted in increased downward pricing pressure on medical services and products, which may affect our ability to sell our products at prices necessary to support our current business strategy. The trend toward health care cost containment through aggregating purchasing decisions and industry consolidation, along with the growth of managed care organizations, is placing increased emphasis on the delivery of more cost- effective medical therapies. For example: • There has been consolidation among health care facilities and purchasers of medical devices, particularly in the United States. One of the results of such consolidation is that group purchasing organizations (GPOs), integrated delivery networks and large single accounts use their market power to consolidate purchasing decisions, which intensifies competition to provide products and services to health care providers and other industry participants, resulting in greater pricing pressures and the exclusion of certain suppliers from important market segments. For example, some GPOs negotiate pricing for their member hospitals and require us to discount, or limit our ability to increase, prices for certain of our products. • Surgeons increasingly have moved from independent, outpatient practice settings toward employment by or affiliation with hospitals and other larger health care organizations, which aligns surgeons' product choices with the institutional providers' price sensitivities and adds to pricing pressures. Hospitals and health care facilities have introduced and may continue to introduce new pricing structures into their contracts to contain health care costs, including fixed price formulas and capitated and construct pricing. • Certain hospitals provide financial incentives to doctors for reducing hospital costs (known as gainsharing), rewarding physician efficiency (known as physician profiling) and encouraging partnerships with health care service and goods providers to reduce costs. • Existing and proposed laws, regulations and industry policies, in both domestic and international markets, regulate or seek to increase regulation of sales and marketing practices and the pricing and profitability of companies in the health care industry.

More broadly, provisions of the Affordable Care Act (ACA) have significantly impacted the way health care is developed and delivered in the United States ~~,~~ and may adversely affect our business and results of operations. We cannot predict accurately what health care programs and regulations will ultimately be implemented at the federal or state level, or the effect of any future legislation or regulation in the United States or elsewhere. However, any changes that have the effect of reducing reimbursement by government health care programs and other third- party payors for procedures using our products or reducing medical procedure volumes could have a material and adverse effect on our business, financial condition and results of operations. Any decline in the amount that payors reimburse our customers for our products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, or if we add more components to our systems, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such ~~increase~~ **increases** with an increase in our prices, our margins could erode. In addition, the largest medical device companies with multiple product franchises have increased their effort to leverage and contract broadly with customers across franchises by providing volume discounts and multi- year arrangements that could prevent our access to these customers or make it difficult, or impossible, to compete on price. Our employees and independent contractors, including independent sales representatives and any other consultants, any future service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. We are exposed to the risk that our employees and independent contractors, including independent sales representatives and any other consultants, any future commercial collaborators, and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate: federal, state, local, or foreign laws and regulations, as well as the laws, regulations and rules of regulatory bodies such as the FDA; manufacturing standards; U. S. federal and state health care fraud and abuse, data privacy laws and other similar non- U. S. laws; or laws that require the true, complete and accurate reporting of financial information or data. It is not always possible to identify and deter misconduct by 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. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U. S. or non U. S. health care programs, other sanctions, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations **.Risks Related to Our** Financial ~~Condition~~ and Capital Requirements **Additional capital** ~~If we fail to manage our growth effectively~~ ~~, our business could~~ **if needed,may not** be ~~materially and adversely affected~~ **available on acceptable terms,if at all** .We **may** ~~have experienced recent rapid growth and anticipate further growth.This growth has placed significant demands on our management,financial,operational,technological and other resources,and we expect that our growth will continue to place significant demands on our management and other resources and will~~ require ~~us~~ **additional capital** to **maintain** ~~continue developing~~ and ~~improving~~ **expand** our ~~operational~~ **operations** ~~,financial and other internal controls .~~ ~~In particular,continued growth~~ **Our operations are capital- intensive and are expected to** ~~increases~~ - **increase as we expand** ~~the challenges involved in a number of areas,including recruiting and retaining sufficient skilled personnel for~~ our ~~direct~~ sales force, **research** ~~providing adequate training~~ and ~~supervision to maintain our high~~ **development efforts and product offerings.If we raise additional funds through the issuance of equity,equity** - **linked** ~~quality standards and preserving our~~ - **or debt securities,those securities may have rights,preferences or privileges senior to those of our common stock,and our existing stockholders may experience dilution.Any debt financing secured by us in the** ~~culture~~ - **future could require that a substantial portion of our operating cash flow be devoted to the payment of interest** and ~~values~~ **principal on such indebtedness,which may decrease available funds for other business activities,and could involve restrictive covenants relating to our capital- raising activities and other financial and operational matters,which may make it more difficult for us to obtain additional capital and to pursue business opportunities.Additionally,any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future.If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties,we may have to relinquish valuable rights to our technologies or product candidates,or grant licenses on terms unfavorable to us** .We **cannot be certain that we will be able to obtain additional financing on favorable terms,if at all.If we cannot raise funds on acceptable terms,if and when needed,we** may not be able to ~~address these challenges in a cost- effective manner,or at all.To achieve our revenue goals,we must also successfully increase our supply of products from third party manufacturers to meet expected customer demand.In the future,we may experience difficulties with quality control,component supply and shortages of qualified personnel,among other problems.These problems could result in delays in product availability and increases in expenses.Any such delay or increased expense could adversely affect our ability to generate revenue.In addition,rapid and significant growth~~ -- **grow** ~~will place a strain on our administrative and operational infrastructure.In order to manage our operations and growth,we will need to continue to improve our operational and management controls,hiring process,reporting and information technology systems and financial internal control procedures.If we do not effectively manage our growth,we may not be able to execute on~~ our business **or** ~~plan,~~ respond to competitive pressures **or unanticipated** ~~,take advantage of market opportunities,satisfy customer~~ requirements ~~or maintain high- quality product offerings~~ ,which could **seriously harm** ~~have a material adverse effect on~~ our business ~~,financial condition and results of operations~~ .The terms of our

loan agreements require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility.If we raise additional capital through debt financing,the terms of any new debt could further restrict our ability to operate our business.Under the terms of our ~~loan~~ **credit** agreements with **Ares Capital** ~~Midcap Financial Trust~~ and Zions Bancorporation discussed in more detail under **the** section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Long- Term Obligations," in Part II of this Annual Report on Form 10- K **,** we are subject to certain affirmative and negative covenants limiting our **and our subsidiaries'** ability to incur certain additional indebtedness,create certain liens **,liquidate or dissolve,amend organizational documents or certain other material contracts** ,enter into a change of control transaction and make certain distributions and investments without our lenders' consent **.Additionally,the Ares Credit Agreement requires that we maintain certain minimum revenue levels tested on a quarterly basis,for the proceeding twelve- month period,commencing with the fiscal quarter ending December 31,2023** .Our lenders may also declare us in default for certain types of events such as non- payment of debts **when due** ,inaccurate representations and warranties,failure to comply with **covenants and obligations,or with** terms **certain other** of material indebtedness ~~and~~ **,certain** material ~~agreements~~ **judgments** ,bankruptcy and insolvency **,impairment of liens** ,a change of control and / or a material adverse ~~change~~ **effect** .Upon such events,our lenders could declare an event of default,which would give them the right to declare all borrowings outstanding,together with accrued and unpaid interest and fees,to be immediately due and payable.In addition,our lenders would have the right to proceed against the assets we provided as collateral under the loan agreements.For example,under our loan agreements,the lenders would have the right to enforce liens and security interests over substantially all of our assets (excluding intellectual property) in the event of certain specified defaults.If the debt under any of our loan agreements is accelerated,we may not have sufficient cash or be able to sell sufficient assets to repay our debts or may have to curtail our growth plans,which would harm our business and financial condition ~~.Additional capital,if needed,may not be available on acceptable terms,if at all.We may require additional capital to maintain and expand our operations.Our operations are capital- intensive and are expected to~~ . Risks Related to Administrative, Organizational and Commercial Operations and Growth If hospitals, ambulatory surgery centers and other health care facilities do not approve the use of our products, our sales may not increase. In order for foot and ankle specialists to use our products at hospitals, ambulatory surgery centers and other health care facilities, we are often required to obtain approval from those hospitals, ambulatory surgery centers and health care facilities. Typically, hospitals, ambulatory surgery centers and health care facilities review the comparative effectiveness and cost of products used in the facility. The makeup and evaluation processes for health care facilities vary considerably, and it can be a lengthy, costly and time- consuming effort to obtain approval by the relevant health care facilities. Additionally, hospitals, ambulatory surgery centers, other health care facilities and GPOs, which manage purchasing for multiple facilities, may also require us to enter into a purchase agreement and satisfy numerous elements of their administrative procurement process, which can also be a lengthy, costly and time- consuming effort. If we do not obtain access to hospitals, ambulatory surgery centers and other health care facilities in a timely manner, or at all, via their approvals or purchase contract processes, or otherwise, or if we are unable to obtain approvals or secure contracts in a timely manner, or at all, our operating costs will increase, our sales may decrease and our operating results may be adversely affected. Furthermore, we may expend significant efforts on these costly and time- consuming processes but may not be able to obtain necessary approvals or secure a purchase contract from such hospitals, ambulatory surgery centers, health care facilities or GPOs. If we fail to receive access to hospital facilities, our sales may decrease. In the United States, in order for physicians to use our products, we expect that the hospital facilities where these physicians treat patients will typically require us to enter into purchasing contracts. This process can be lengthy and time- consuming and require extensive negotiations and management time. In the European Union (EU) certain institutions may require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may decrease **,** and our operating results may be harmed. Furthermore, we may expend significant effort in these time- consuming processes and still may not obtain a purchase contract from such hospitals. Performance issues, service interruptions or price increases by shipping carriers could adversely affect our business and harm our reputation and ability to provide our products on a timely basis. Expedited, reliable shipping will be essential to our operations. We intend to rely heavily on providers of transport services for reliable and secure point- to- point transport of our products to our customers and for tracking ~~of~~ these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of our products, it would be costly to replace our products in a timely manner, could cause surgeries using our products to be delayed or canceled and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis. If coverage or adequate levels of reimbursement from third- party payors for procedures using our products, or any future products we may seek to commercialize, are not obtained or maintained, foot and ankle specialists and patients may be reluctant to use our products and our business will suffer. In the United States, health care providers who purchase our products generally rely on third- party payors, principally federally- funded Medicare, state- funded Medicaid and private health insurance plans, to pay for all or a portion of the cost of foot and ankle procedures and products utilized in those procedures. We may be unable to sell our products, or any future products we may seek to commercialize, on a profitable basis if third- party payors deny coverage or reduce their current levels of reimbursement for procedures using our products. Payors continue to review their coverage policies for existing and new therapies and may deny coverage for treatments that include the use of our products or any future products we may seek to commercialize. Third- party payors, whether foreign or domestic, or

governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our solution exists among third- party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. In addition, some health care providers in the United States have adopted or are considering bundled payment methodologies and / or managed care systems in which providers contract to provide comprehensive health care for a fixed cost per person. Health care providers may attempt to control costs by authorizing fewer elective surgical procedures, including foot and ankle surgeries, or by requiring the use of the least expensive procedure available. In addition, third- party payors increasingly are requiring evidence that medical devices are cost- effective, and if we are unable to meet this requirement, the third- party payor may not cover procedures using our products, which could reduce sales of our products to health care providers who depend upon third- party payor reimbursement for payment. Changes in coverage policies or health care cost containment initiatives that limit or restrict reimbursement for procedures using our products may have an adverse effect on our business. Outside of the United States, reimbursement levels vary significantly by country and by patient. Reimbursement is obtained from a variety of sources, including government sponsors, hospital budgets, public tenders / bids, or private health insurance plans, or combinations thereof. We participate in and have established appropriate market access in countries where required and applicable. Uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices and foreign regulations that might prohibit the use of certain of our products, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices. The majority of our sales force consists of independent sales representatives, and if we are unable to maintain and expand our network of independent sales representatives, we may be unable to generate anticipated sales. Our revenue and profitability ~~is~~ **are** directly dependent upon the sales and marketing efforts of our sales force. We utilize a sales force comprised primarily of independent sales representatives to sell our products to surgeons, hospitals, clinics, foot and ankle specialists and other end users and to assist us in promoting market acceptance of, and creating demand for, our products and procedures. As we increase our marketing efforts, we will need to retain, develop and grow the number of sales representatives that we employ. We intend to make a significant investment in recruiting and training sales representatives and clinical representatives as we expand our business. There is significant competition for sales personnel experienced in relevant medical device sales. If we are unable to come to commercially reasonable terms with a sales representative or representatives, we may not generate the expected level of sales and may need to spend more of our capital resources to hire sales personnel as employees. Once hired, the training process can be lengthy because it requires significant education for new sales representatives and to achieve the level of clinical competency with our products expected by foot and ankle specialists. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products often requires or benefits from direct support from us, including through our sales representatives that provide assistance in the operating room. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could negatively affect our business, financial condition and results of operations. Even if we are able to attract and retain additional sales representatives, in situations where our sales representatives are not exclusive to us, there is a risk that a sales ~~representatives~~ **representative** that we contract with will give higher priority to the products of other medical device companies, including products directly competitive with our products or may be required by larger medical devices companies to stop offering our products. Though we have established initiatives to further focus our independent sales channel on our products, these initiatives may not translate to the increase **in** sales or penetration which we expect. There can be no assurance that a sales ~~representatives~~ **representative** will devote the resources necessary to provide effective sales and promotional support to our products. Also, to the extent we engage sales representatives from our competitors, we may have to wait until applicable non- competition provisions or obligations have expired. Notwithstanding the foregoing, we may still be subject to future allegations that these new hires have been improperly solicited, and that they have divulged to us proprietary or other confidential information of their former employers. Additionally, because the market for experienced sales personnel is competitive, our competitors may try to hire our sales representatives away from us. If successful, we would be required to dedicate resources to recruiting, filling and training those vacant positions. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations. We depend on third- party contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our foot and ankle products, and if these suppliers and manufacturers fail to supply us, our products or their components or subcomponents in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition, and results of operations. We utilize qualified medical device contract manufacturers and suppliers, some of which are single sources, to produce and package all elements comprising our foot and ankle products. Our significant single source suppliers include Tech Metals, which supplies parts used in our Gorilla plating system, QTS, which provides cleaning, packaging and sterilization services for multiple of our products, 3D Systems, which supplies parts used in our APEX 3D Total Ankle Replacement system, Seaway, which supplies parts for our drill guides and Orchid, which supplies parts used in our Apex Talus Implants. While we estimate replacing these single source suppliers could take up to approximately six months, in some of these examples alternative second source suppliers may not be readily available. We seek to strategically maintain sufficient levels of inventory to help mitigate supply disruption, usually holding sufficient inventory to allow for manufacturing from 90 to 180 days following the loss of a supplier, to accommodate varying demand mix and to achieve more efficient volume- based

pricing on our components; however, we may not be accurate in our estimates which could result in insufficient inventory to meet demand or excess inventory and the risk of inventory obsolescence and expiration. Further, while we have entered into several supply agreements in an effort to reinforce our supply chain, there is no guarantee the counter- party suppliers will adhere to the terms of these agreements. Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third- party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on a third- party manufacturer and third- party suppliers also subjects us to other risks that could harm our business that we would not be subject to if we manufactured products ourselves, including, among others: • we may not be a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours; • third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us; • we may not be able to obtain an adequate supply of components in a timely manner or on commercially reasonable terms; • our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause delays in shipment; • we may have difficulty locating and qualifying alternative suppliers; • switching components or suppliers may require product redesign and possibly submission to FDA, notified bodies, or other foreign regulatory bodies, which could significantly impede or delay our commercial activities; • one or more of our single- source suppliers may be unwilling or unable to supply components of our products; • other customers may use fair or unfair negotiation tactics or pressures to impede our use of the suppliers; • the occurrence of a fire, natural disaster or other catastrophe, or the occurrence of geopolitical conflicts such as the war between Ukraine and Russia, as well as any sanctions or other actions resulting therefrom, impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; • ~~the impact~~ **a resurgence** of COVID- 19 may impact a manufacturing facility by limiting operating capacity or sideline critical employees involved in the manufacturing processes thereby affecting their ability to deliver products to us in a timely manner; • our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements; • our suppliers may not maintain the confidentiality of our proprietary information; and • higher manufacturing and product costs than more vertically integrated companies. Any of these factors could cause delay or suspension of commercialization and marketing, regulatory submissions or required approvals, clearances or certifications, or cause us to incur higher costs. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of finished products on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. Any difficulties in locating and hiring third- party manufacturers, or in the ability of third- party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business. It may take a significant amount of time and resources (including costs) to establish an alternative source of supply for our products and to have any such new source authorized by the FDA or foreign regulatory authorities or notified bodies. Given our reliance on certain single- source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country- specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may have a material adverse effect on our business, financial condition, and results of operations. Any of these matters could materially and adversely affect our business, financial condition, and results of operations. Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory. Given the large variety and number of products we sell, in order to market and sell them effectively, we must maintain significant levels of inventory and surgical instrumentation. As a result, a significant amount of our cash used in operations has been associated with maintaining these levels of inventory. To ensure adequate inventory supply, we must forecast inventory needs and manufacture our products based on our estimates of future demand. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write- downs or write- offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our ~~product~~ **products**, our internal manufacturing team may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or may not be able to allocate sufficient capacity in order to meet our increased requirements, which will negatively affect our business, financial condition and results of operations. We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory obsolescence charges and costs required to replace such inventory. 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, product improvements or the generation of significant future revenues. 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 new products or product improvements 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 viable product improvements or result in significant revenues 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 future collaborators, they may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. 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 may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense. Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. For example, in early 2022 we acquired Disior Oy. Our ability to realize the potential benefits of this acquisition and to integrate the acquired assets may not be successful or may not occur within our anticipated timeline. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including: • difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations; • issues maintaining uniform standards, procedures, controls and policies; • unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write- offs of intangible assets or goodwill; • diversion of management' s attention from our core business and disruption of ongoing operations; • adverse effects on existing business relationships with suppliers, sales representatives, health care facilities, foot and ankle specialists and other health care providers; • risks associated with entering new markets in which we have limited or no experience; • potential losses related to investments in other companies; • potential loss of key employees of acquired businesses; • unanticipated or undisclosed liabilities of any target; and • increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters. We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if 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, sales representative, health care facilities, surgeons or other health care providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products 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 pursue any foreign acquisitions, they typically involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries. To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all. We may not be able to establish or strengthen our brand. We believe that establishing and strengthening Paragon 28 and our various foot and ankle procedure brands, including Smart 28, is important to achieving widespread acceptance of our foot and ankle products and procedures, particularly because of the highly competitive nature of

the market for similar products. We believe the quality and reliability of our products is critical to building physician support for our foot and ankle products and solutions in the United States and abroad, and any negative publicity regarding the quality or reliability of our products and procedures could significantly damage our reputation in the market. In the course of conducting our business, we must adequately address quality issues that may arise with our products, including defects in third- party components included in our products. Although we have established internal procedures designed to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of our products ~~do~~ **does** not meet the expectations of physicians or patients. In addition, promoting and positioning our brand will depend largely on the success of our medical education efforts and our ability to educate foot and ankle specialists and patients. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our foot and ankle solutions may not be accepted by physicians or patients, which would adversely affect our business, results of operations and financial condition. Our inability to maintain contractual relationships with health care professionals could have a negative impact on our research and development and medical education programs. We maintain contractual relationships with respected physicians and medical personnel in hospitals, private practice and universities who assist in clinical studies, product research and development and in the training of foot and ankle specialists on the safe and effective use of our products. We continue to place emphasis on the validation of the benefits of our foot and ankle products and procedures through clinical studies, the development of proprietary products and product improvements to develop our product lines as well as providing high quality training on those products. If we are unable to maintain these relationships, our ability to develop and market new and improved products and train on the use of those products could decrease, and future operating results could be unfavorably affected. At the same time, the medical device industry' s relationship with physicians is under increasing scrutiny by the U. S. Department of Health and Human Services Office of Inspector General (OIG), the U. S. Department of Justice (DOJ), the state attorneys general and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry' s relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorneys general and other government agencies, could negatively affect our business, financial condition and results of operations. See " Risk Factors — Risks Related to Regulatory Matters — Our relationships with customers, foot and ankle specialists and third- party payors are subject to federal and state health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws we could face substantial penalties. " We may be unable to continue to successfully demonstrate to foot and ankle specialists or key opinion leaders the merits of our products and technologies compared to those of our competitors, which may make it difficult to establish our products and technologies as a standard of care and achieve market acceptance. Foot and ankle specialists play the primary role in determining the course of treatment and, ultimately, the type of products that will be used to treat a patient. As a result, our success depends, in large part, on our ability to effectively market and demonstrate to foot and ankle specialists the merits of our products and methodologies compared to those of our competitors. Acceptance of our products and methodologies depends on educating foot and ankle specialists as to the distinctive characteristics, clinical benefits, safety and cost-effectiveness of our products, procedures and technologies as compared to those of our competitors, and on training foot and ankle specialists in the proper use of our products. If we are not successful in convincing foot and ankle specialists of the merits of our products and methodologies or educating them on the use of our products, they may not use our products or may not use them effectively and we may be unable to increase our sales, sustain our growth or achieve and sustain profitability. Also **,** since a number of our foot and ankle procedures and products are new, some foot and ankle specialists may be reluctant to change their surgical treatment practices for the following reasons, among others: • lack of experience with our products and procedures; • existing relationships with competitors and distributors that sell competitive products; • lack or perceived lack of evidence supporting additional patient benefits; • perceived liability risks generally associated with the use of new products and procedures; • less attractive availability of coverage and reimbursement by third- party payors compared to procedures using competitive products and other techniques; • costs associated with the purchase of new products and equipment; and • the time commitment that may be required for training. These reasons may affect the pace of adoption of our foot and ankle products and procedures and future products and techniques that we may offer. In addition, we believe recommendations and support of our products and technologies by surgeons, foot and ankle specialists and other key opinion leaders in our industry are essential for market acceptance and establishment of our products and procedures as a standard of care. If we do not receive support from such surgeons, foot and ankle specialists and other key opinion leaders, if long- term data does not show the benefits of using our products and procedures or if the benefits offered by our products and procedures are not sufficient to justify their cost, foot and ankle specialists, hospitals and other health care facilities may not use our products and we might be unable to establish our products and procedures as a standard of care and continue to achieve market acceptance. If foot and ankle specialists fail to safely and appropriately use our products, or if we are unable to train podiatrists and orthopedic surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected sales, growth or profitability. An important part of our sales process includes our ability to screen for and identify podiatrists and orthopedic surgeons who have the requisite training and experience to safely and appropriately use our products and to train a sufficient number of these foot and ankle specialists and to provide them with adequate instruction in use of our products. There is a training process involved for foot and ankle specialists to become proficient in the safe and appropriate use of our products. This training process may take longer or be more expensive than expected. Convincing foot and ankle specialists to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts. Recent changes to federal guidance regarding medical education programs under the federal Anti- Kickback Statute also could limit our ability to train podiatrists and orthopedic

surgeons, and such programs could be subject to challenge under the federal Anti- Kickback Statute. See " Risk Factors — Risks Related to Regulatory Matters — Our relationships with customers, foot and ankle specialists and third- party payors are subject to federal and state health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws we could face substantial penalties. " Furthermore, if clinicians are not properly trained, they may misuse or ineffectively use our products. Any improper use of our products may result in unsatisfactory outcomes, patient injury, negative publicity or lawsuits against us, any of which could harm our reputation and affect future product sales. Accordingly, if foot and ankle specialists fail to safely and appropriately use our products or if we are unable to train foot and ankle specialists on the safe and appropriate use of our products, we may be unable to achieve our expected sales, growth or profitability. The loss of any member on our executive management team or our inability to attract and retain highly skilled members of our sales management and marketing teams and engineers could have a material adverse effect on our business, financial condition and results of operations. Our success depends on the skills, experience and performance of the members of our executive management team including Albert DaCosta, our ~~co~~ **Co** - ~~founder~~ **Founder** , ~~chairman~~ **Chairman** , ~~president~~ **President** and ~~chief~~ **Chief** ~~executive~~ **Executive** ~~officer~~ **Officer** , in particular. The individual and collective efforts of these executives will be important as we continue to commercialize our existing products, develop new products and technologies and expand our commercial activities. The loss or incapacity of existing members of our executive management team could have a material adverse effect on our business, financial condition and results of operations if we experience difficulties in hiring qualified successors. We do not maintain " key person " insurance for any of our executives or key employees. Our commercial, quality and research and development programs and operations depend on our ability to attract and retain highly skilled team members. We may be unable to attract or retain qualified team members. All of our U. S. employees are at- will, which means that either we or the employee may terminate his or her employment at any time. The loss of key employees, failure of any key employee to perform, our inability to attract and retain skilled employees, as needed, or our inability to effectively plan for and implement a succession plan for key employees could have a material adverse effect on our business, financial condition and results of operations. Risks Related to Our Intellectual Property If we or our licensors are unable to obtain and maintain significant patent or other intellectual property protection for our products, or if the scope of our patents and other intellectual property rights is not sufficiently broad and does not adequately protect our products, our competitors could develop and commercialize products similar or identical to ours and we may be unable to gain significant market share and be unable to operate our business profitably. Our success depends in large part on our and our licensors' ability to obtain, maintain and solidify a proprietary position for our products, which will depend on our and our licensors' success in obtaining effective intellectual property protection, including through patents, trade secrets, copyrights, know- how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not completely protect our rights. Any failure to obtain or maintain patent and other intellectual property protection with respect to our products could harm our business, financial condition and results of operations. As of December 31, ~~2022~~ **2023** , our patent portfolio included ~~262~~ **304** owned and registered patents and ~~11~~ **26** in- licensed patents. **Seventy** ~~Fifty- six~~ of these patents are U. S. utility patents. As of December 31, ~~2022~~ **2023** , we had ~~231~~ **265** pending patent applications globally, including ~~74~~ **87** in the United States. Outside of the United States we have patent applications pending in Europe, Australia, Canada, South Africa, Brazil, and Japan as well as through our PCT applications (which have been counted as pending U. S. patent applications). We cannot assure that our intellectual property position will not be challenged or that all patents for which we have applied will be granted. The validity and breadth of claims in patents involve complex legal and factual questions and, therefore, may be highly uncertain. Uncertainties and risks that we face include the following: • our pending or future patent applications may not result in the issuance of patents; • the scope of any existing or future patent protection may not exclude competitors or provide competitive advantages to us; • our patents may not be held valid or enforceable if subsequently challenged; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in- license will result in issued patents with claims that cover our products or uses thereof in the United States or in other foreign countries; • the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property; • we may fail to adequately protect and police our trademarks and trade secrets; • other parties may claim that our products and designs infringe the proprietary rights of others — even if we are successful in defending our patents and proprietary rights, the cost of such litigation may adversely affect our business; and • other parties may develop similar products, duplicate our products, or design around our patents. The patent prosecution process is expensive and time- consuming, and we and our licensors may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, any of these parties may inadvertently or intentionally breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our developments before it is too late to obtain patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our

inventions and the prior art allow our inventions to be patented over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until eighteen (18) months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, certain countries outside of the United States do not allow patents for methods of treating the human body. This may preclude us from obtaining method patents outside of the United States having similar scope to those we have obtained or may obtain in the future in the United States. This includes certain key method patents covering our procedures and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our patent rights and, more generally, could affect the value of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or third parties. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad, and as a result, may not provide us with adequate proprietary protection or competitive advantage against competitors with similar products. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and Trademark Office (USPTO) or patent offices in foreign jurisdictions, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques without payment to us, or limit the duration of the patent protection of our technology. We cannot ensure that we do not infringe any patents or other proprietary rights held by third parties. If our products were found to infringe any proprietary right of another party, we could be required to pay significant damages or license fees to such party and / or cease production, marketing and distribution of those products. Litigation may also be necessary to defend infringement claims of third parties or to enforce patent rights we hold or to protect trade secrets or techniques we own. In addition, because patent applications can take many years to issue , and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. We also rely on trade secrets and other unpatented proprietary technology. There can be no assurances that we can meaningfully protect our rights in our trade secrets and other unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our proprietary technology. We seek to protect our trade secrets and proprietary know- how and technology, in part, with confidentiality and invention assignment agreements with employees and consultants that include confidentiality obligations and valid, present-tense intellectual property assignment obligations. There can be no assurances, however, that the agreements will not be breached, adequate remedies for any breach would be available or competitors will not discover our trade secrets or independently develop comparable intellectual property. Further, litigation may be necessary to obtain ownership or to defend against claims challenging ownership. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees, and such claims could harm our business, financial condition and results of operations. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, and are therefore reliant on our licensors and may be reliant on future licensors or licensees, to protect certain intellectual property used in our business. If our licensors or future licensors or licensees fail to adequately protect this intellectual property, our ability to commercialize products could suffer. For example, we rely on a current licensor to maintain the patents and otherwise protect the intellectual property we license pursuant to a license agreement with such third party. Such licensor may not successfully prosecute, maintain and protect such patents and intellectual property or may determine not to pursue litigation against third- parties that are infringing these rights, or may pursue litigation less aggressively than we would. Some of our patents and patent applications may in the future be jointly owned with third parties. If we are unable to obtain an exclusive license to any such third party joint owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such joint owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations. Obtaining and maintaining intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental agencies, and our intellectual property protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and / or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and / or patent application. The USPTO, the United States Copyright Office (USCO) and various foreign governmental agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the intellectual property application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on intellectual property registrations often must be paid to the USPTO, USCO and foreign agencies over the lifetime of the intellectual property registration and / or application and any intellectual property rights we may obtain in the future. While an unintentional lapse of an intellectual property registration or application ~~, including due to the effect of the COVID- 19 pandemic~~ on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in

accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the registration or application, resulting in partial or complete loss of intellectual property rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a registration or application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the intellectual property registrations and applications covering our products, we may not be able to stop a competitor from developing and marketing products that are the same as or similar to our products, which would have a material adverse effect on our business. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. We have not performed comprehensive searches or analyses of third- party patents that may be relevant to our technology and products. We may not be able to conduct complete and thorough searches, we may not be able to identify all relevant third- party patents, and we may not be able to fully predict the scope of the patent claims or the expiration of relevant third- party patent applications that may issue as patents. We cannot be certain that we are aware of all third- party patents and pending applications in the United States and abroad that are relevant to or necessary for the commercialization of our products in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third- party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products. Our business also would suffer if any future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us , and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. We are dependent on patents and other intellectual property licensed from others and may become dependent on other patents or other intellectual property licensed from others in the future. If we lose our licenses for intellectual property that is important to our business, we may not be able to continue developing or selling our products. We have obtained licenses that give us rights to third party intellectual property, including patents and know- how, that is necessary or useful to our business. The license agreements covering our products impose various obligations on us, including the obligation to pay certain royalties on sales of certain of our products. One or more of our licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license. As a result, we may not be able to market products that were covered by the license, which would result in the loss of significant rights, restrict our ability to commercialize certain of our products and could adversely affect our competitive business position and harm our business prospects. In addition, any claims brought against us by our licensors could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Licensing of intellectual property involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under license agreements and other interpretation- related issues; • the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to license agreements; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by any of current or future our licensors and us and our partners; and • the priority of invention of patented technology. If disputes over intellectual property that we have or may in the future license prevent or impair our ability to maintain our current or future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we may license as we are for intellectual property that we own. If we or any of our current or future licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. We have previously been party to lawsuits involving patents and other intellectual property and the possibility exists that we may in the future be party to other lawsuits or administrative proceedings involving patents or other intellectual property. If we were to lose any intellectual property lawsuits, a court could require us to pay significant damages and / or prevent us from selling our products. The medical device industry is highly competitive and litigious with respect to patents, trademarks, trade secrets, and other intellectual property rights. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Our commercial success depends in part upon our ability and that of our contract manufacturers and suppliers to manufacture, market, and sell our products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual

property rights with respect to our products and any future products and technology, whether or not we are actually infringing, misappropriating or otherwise violating the rights of third parties. We may in the future be party to other lawsuits or other administrative proceedings involving our patents or other intellectual property, regardless of merit. A legal proceeding, regardless of the outcome, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, could drain significant financial resources and divert the time and effort of our management. Protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue selling, developing and marketing our products and techniques. However, we may not be able to obtain any required license on commercially reasonable terms or at all. The acquisition or licensing of third- party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third party intellectual property rights that we may consider attractive or necessary. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant products or redesign those products that contain the allegedly infringing intellectual property, which could harm our business, financial condition and results of operations. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline. Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming, and could distract our technical and management personnel from their normal responsibilities. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims that our patents are invalid or unenforceable or file administrative actions against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding or administrative action could put one or more of our patents at risk of being invalidated or interpreted narrowly. Our competitors may assert invalidity on various grounds, including lack of novelty, obviousness, non- enablement, lack of written description or that we were not the first applicant to file a patent application related to our product. We may elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes before litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. Our competitors, many of which have made substantial investments in patent portfolios, trade secrets, trademarks and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that may prevent, limit or otherwise interfere with our ability to make, use, sell and / or export our products or to use our technologies or product names. Moreover, individuals and groups that are non- practicing entities, commonly referred to as " patent trolls, " purchase patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or " invitations to license, " or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management' s attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Further, the outcome of litigation is uncertain and such litigation could result in us being forced to stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property; pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing; redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive, or infeasible; and / or attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms, or at all, or, from third parties. In addition, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or indemnify our customers for any costs associated with their own initiation or defense of infringement claims, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products. If we fail to execute invention assignment agreements with our employees and contractors involved in the development of intellectual

property or are unable to protect the confidentiality of our trade secrets, the value of our products and our business and competitive position could be harmed. In addition to patent protection, we also rely on the protection of trademarks, copyrights, trade secrets, unpatented know- how, technology and other confidential and proprietary information to maintain our competitive position. We generally enter into confidentiality and invention assignment agreements with our employees, consultants and third parties upon their commencement of a relationship with us. However, we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property. In addition, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition and results of operations. In particular, a failure to protect our proprietary rights may allow competitors to copy our products and procedures, which could adversely affect our pricing and market share. Further, other parties may independently develop substantially equivalent know- how and technology. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. While we have agreements with our employees, consultants and third parties that obligate them to assign their inventions to us, these agreements may not be self- executing, not all employees or consultants may enter into such agreements, or employees or consultants may breach or violate the terms of these agreements, and we may not have adequate remedies for any such breach or violation. If any of our intellectual property or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be harmed. 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 guarantee that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. Our registered and unregistered trademarks, trade names, and brand names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks, trade names, and brand names which we rely upon to build name recognition among potential partners and customers in our markets of interest. 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, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. We may also license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Patent terms may not be sufficient to effectively protect our products and business for an adequate period of time. Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a utility patent is generally 20 years after its first effective non- provisional filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Even if patents covering our proprietary technologies and their uses are obtained, once the patent has expired, we may be open to competition, which may harm our business prospects. In addition, although upon issuance in the United States a patent' s term can be extended based on certain delays caused by the USPTO, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable

deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. If we do not have sufficient patent terms to protect our products, proprietary technologies and their uses, our business would be seriously harmed. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our reduced patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Changes in U. S. or foreign patent laws or their interpretation may limit our ability to obtain, maintain, defend and / or enforce our patents. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy- Smith America Invents Act (Leahy- Smith Act) includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO has developed regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first- to- file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy- Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board (PTAB), provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long- term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U. S. patent claims. The availability of the PTAB as a lower- cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. The America Invents Act also includes a number of significant changes that affect the way U. S. patent applications will be prosecuted and also may affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by the USPTO administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U. S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations. We have limited foreign intellectual property rights and may be unable to enforce our intellectual property rights throughout the world. We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents or trademarks on our products and any future products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions or utilizing our trademarks in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection , but enforcement is not as strong as that in the United States. These products may compete with our products and any future products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing in these jurisdictions. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. We are and in the future may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know- how, or are in breach of non- competition or non- solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property that we regard as our own. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Many of our employees and consultants were previously employed at or engaged by other medical device companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have

executed proprietary rights, non- disclosure and non- competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. Additionally, we may be subject to claims that former employees, collaborators or other third parties have an ownership interest in or inventorship of intellectual property we regard as our own, for example, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to defend against and resolve claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from using technologies, features or other intellectual property that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our third- party manufacturing partners do not respect our intellectual property and trade secrets and produce competitive products using our designs or intellectual property, our business, financial condition and results of operations would be harmed. Although our agreements with third- party manufacturing partners generally seek to prevent them from misusing our intellectual property and trade secrets, or using our designs to manufacture products for our competitors, we may be unsuccessful in monitoring and enforcing our intellectual property rights against these manufacturing partners and may find counterfeit goods in the market being sold as our products or future products similar to ours produced for our competitors using our intellectual property. Although we take steps to stop counterfeits, we may not be successful and network operators who purchase these counterfeit goods may experience product defects or failures, harming our reputation and brand and causing us to lose future sales. Any of the foregoing could harm our business, financial condition and results of operations. We are subject to substantial government regulation that could have a material adverse effect on our business. Our products and our business are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U. S. and foreign regulations govern the design, development, testing, clinical studies, premarket clearance, approval, certifications, safety, registration, manufacturing, packaging, storage, reporting, sales, distribution, marketing, labeling, promotion, relationships with health care professionals, recordkeeping procedures, post- marketing surveillance, post- market studies, and product import and export of our products. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot be assured that any of our products will be authorized for marketing. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and other regulatory authorities enforce these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections. Moreover, the FDA and other authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in: • adverse publicity, warning letters, untitled letters, or " it has come to our attention " letters from the FDA, or similar letters from foreign regulatory authorities alleging noncompliance; • fines, penalties, injunctions, or consent decrees; • operating restrictions, partial suspension or total shutdown of production; • denial of requests for regulatory clearance, approval or certification of new products, new intended uses or modifications to existing products; • repair, replacement, refunds, recalls, or seizures of our products; or • withdrawal or suspension of regulatory clearance, approval or certification that have already been granted and / or obtained. Any of these events could result in ~~a~~ higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. Our relationships with customers, physicians and third- party payors are subject to federal, state, and foreign health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws, we could face substantial penalties. Our relationships with customers, physicians and third- party payors are subject to federal, state, and foreign health

care fraud and abuse laws, false claims laws, transparency laws with respect to payments and other transfers of value made to physicians and other licensed health care professionals, and other health care laws and regulations. In particular, the promotion, sales and marketing of health care items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. The U. S. health care laws and regulations that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal health care programs. The term " remuneration " has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that may be alleged to be intended to induce the purchases or recommendations ~~,~~ include any payments of more than fair market value ~~,~~ **and** may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation; • federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal health care programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act; • the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which created new federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, including private third- party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, health care benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and • state and foreign equivalents of each of the health care laws described above, among others, some of which may be broader in scope including, without limitation, state anti- kickback and false claims laws that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non- governmental third party payors, including private insurers, or that apply regardless of payor; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other health care providers, marketing expenditures; and state and local laws requiring the registration of device sales and medical representatives. Greater scrutiny of marketing practices in the medical device industry has resulted in numerous government investigations by various government authorities, and this industry- wide enforcement activity is expected to continue. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different and difficult compliance and reporting requirements, increases the possibility that we may run afoul of one or more laws. The costs to comply with these regulatory requirements are becoming more expensive and will also impact our profitability. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, patient outreach programs or our arrangements with independent sales representatives and customers could be subject to challenge under one or more of such laws. We have also entered into consulting and royalty agreements with physicians, including some who have ownership interests in us and / or influence the ordering of or use our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. We could be adversely affected if regulatory agencies determine our financial relationships with such physicians to be in violation of applicable laws. Greater scrutiny of marketing practices in the medical device industry has resulted in numerous government investigations by various government authorities, and this industry- wide enforcement activity is expected to continue. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different and difficult compliance and reporting requirements, increases the possibility that we may run afoul of one or more laws. The costs to comply with these regulatory requirements are becoming more expensive and will also impact our profitability. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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 we or our employees, agents, independent contractors, consultants, commercial partners and vendors violate these

laws, we may be subject to investigations, enforcement actions and / or significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and / or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and / or curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We may not receive, or may be delayed in receiving, the necessary clearances, approvals or certifications for our future products or modifications to our current products, and failure to timely obtain necessary clearances, approvals or certifications for our future products or modifications to our current products would adversely affect our ability to grow our business. In the United States, before we can market a new medical device, or a new use of, **or** new claim for or significant modification to an existing medical device product, we must first receive either clearance under Section 510 (k) of the Federal Food, Drug, and Cosmetic Act (FDCA) or ~~approval of~~ a ~~premarket approval (~~ PMA ~~),~~ from the FDA, unless an exemption applies **,** or we qualify for de novo classification. In the 510 (k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is " substantially equivalent " to a legally- marketed " predicate " device, which includes a device that has been previously cleared through the 510 (k) process, a device that was legally marketed before May 28, 1976 (pre- amendments device), a device that was originally on the U. S. market pursuant to **a** ~~an approved~~ PMA and later down-classified, or a 510 (k)- exempt device. To be " substantially equivalent, " the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining **a** PMA ~~approval~~, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre- clinical, clinical trial, manufacturing and labeling data. 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. In the de novo classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down- classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the de novo classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510 (k) submissions. We also acquired the total talus spacer, which has been authorized for marketing pursuant to an approved Humanitarian Device Exemption (HDE). An HDE allows for marketing of a Humanitarian Use Device, or HUD, which is a medical device designated by the FDA as intended to benefit patients in the treatment or diagnosis of a disease or condition that affects not more than 8, 000 individuals in the United States per year. To market a HUD, the device must have received a HUD designation by the FDA and be approved by the FDA pursuant to an HDE application. An HDE approval is based on the applicant' s demonstration that there is no comparable device available and that the probable benefit to health from the proposed HUD outweighs the risk of injury or illness from its use, taking into account alternative treatments that are available for the condition or disease. However, a medical device approved pursuant to an HDE is exempt from the effectiveness requirements that would otherwise apply and to which the device would be subject if approved pursuant to a PMA, and clinical studies demonstrating effectiveness are not required to support approval. An approved HDE must be labeled with a disclaimer stating that the effectiveness of the device has not been established. In addition, HUDs that receive HDE approval may not be sold for profit except in limited circumstances. In any case, to sell the device for profit, HDE holders must notify the FDA of the intent to sell for profit and are limited in the number of devices that may be sold for profit on an annual basis. Prior to HUD use following HDE approval, the HDE holder is required to ensure that use of the use of the HUD has been approved by the facility' s IRB. Post- approval clinical studies may also be required. Our total talus spacer is subject to the requirement for a post- approval study as a condition of approval of the HDE. Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through an HDE require FDA approval, and products cleared through a 510 (k) or authorized for marketing pursuant to a de novo classification may require a new 510 (k) clearance. The marketing authorization process can be expensive, lengthy and uncertain. The FDA' s 510 (k) clearance process usually takes from three to ~~12~~ **nine** months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510 (k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device. In the United States, except for the total talus spacer, we have obtained clearance of all of our non-exempt products through the 510 (k) clearance process. Any modification to these products that has not been previously cleared may require us to submit a new 510 (k) premarket notification and obtain clearance, or submit ~~a~~ **for** PMA and obtain FDA approval, before implementing the change. Specifically, 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, ~~approval of~~ a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer' s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to 510 (k)- cleared products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510 (k) clearances or **a** PMA ~~approvals~~ were not required. We may make modifications or add additional features in the future that we believe do not require a new 510 (k) clearance or ~~approval of~~ a PMA. If the FDA disagrees with our determination and requires

us to submit new 510 (k) premarket notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. The FDA, applicable foreign regulatory authorities and Notified Body can delay, limit or deny clearance, approval or certification of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or Notified Body that our products are safe or effective for their intended uses; • the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or clinical studies or the interpretation of data from pre- clinical studies, clinical trials or clinical studies; • serious and unexpected adverse device effects experienced by participants in our clinical trials or clinical studies; • our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; • the manufacturing process or facilities we use may not meet applicable requirements; and • the potential for approval or certification policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance, approval or certification. Until May 25, 2021, medical devices were regulated by the Council Directive 93 / 42 / EEC (EU Medical Devices Directive) which has been repealed and replaced by Regulation (EU) No 2017 / 745 (EU Medical Devices Regulation) which became effective on May 26, 2021. Our current certificates have been granted and renewed under the EU Medical Devices Directive. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021, may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no significant change must be made to the device in question. However, as of May 26, 2021, we must comply with the EU Medical Devices Regulation requirements applying in place of the corresponding requirements of the EU Medical Devices Directive with regard to registration of economic operators and of devices, post- market surveillance, market surveillance and vigilance requirements. Pursuing marketing of medical devices in the EU will notably require that our devices be certified under the new regime set forth in the EU Medical Devices Regulation when our current certificates expire. If we fail to comply with applicable EU legislation, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EU and the European Economic Area (EEA) (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland). Non- compliance with the above regulations would also prevent us from selling our products in these three countries. Following Brexit, EU laws no longer apply directly in Great Britain. The regulations on medical devices in Great Britain continue to be based largely on the three EU Directives which preceded the EU Medical Devices Regulation, as implemented into national law. However, under the terms of the Protocol on Ireland / Northern Ireland, the EU Medical Devices Regulation does apply to Northern Ireland. Consequently, there are currently different regulations in place in Great Britain as compared to both Northern Ireland and the EU, respectively. Ongoing compliance with both sets of regulatory requirements may result in increased costs for our business. Furthermore, the United Kingdom (UK) Government is currently drafting amendments to the existing legislation which is likely to result in further changes to the Great Britain regulations in the near future. For example, subject to transitional periods for validly- certified devices, the new Great Britain regulations are likely to require medical devices and IVDs placed on the Great Britain market to be " UKCA " certified by a UK Approved Body in order to be lawfully placed on the market. The UK Government has stated that the amended regulations are likely to apply from July 2024; understanding and ensuring compliance with any new such requirements is likely to lead to further complexity and increased costs to our business. If there is insufficient UK Approved Body capacity, there is a risk that our product certification could be delayed which might impact our ability to market products in Great Britain after the respective transition periods. We also market certain products that are comprised of human cells, tissues and cellular or tissue- based products (HCT / P). In the U. S., we are marketing our HCT / Ps pursuant to Section 361 of the PHSA and 21 CFR Part 1271 of FDA' s regulations. We do not manufacture these HCT / P products, but serve as a distributor for them. So- called Section 361 HCT / Ps are not currently subject to the FDA requirements to obtain marketing authorizations as long as they meet certain criteria provided in FDA' s regulations. HCT / Ps regulated as " 361 HCT / Ps " are currently subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, current good tissue practice requirements, or cGTPs, when processing, storing, labeling and distributing HCT / Ps, including required labeling information, stringent record keeping and adverse event reporting. If we or our suppliers fail to comply with these requirements, we could be subject to FDA enforcement action, including, for example, warning letters, fines, injunctions, product recalls or seizures, and, in the most serious cases, criminal penalties. To be regulated as Section 361 HCT / Ps, these products must meet FDA' s criteria to be considered " minimally manipulated " and intended for " homologous use, " among other requirements. HCT / Ps that do not meet the criteria to be considered Section 361 HCT / Ps are subject to the FDA' s regulatory requirements applicable to medical devices, orthobiologics or drugs. Device, orthobiologic or drug HCT / Ps must comply both with the requirements exclusively applicable to Section 361 HCT / Ps and, in addition, with other requirements, including requirements for marketing authorization. For example, Section 361 HCT / Ps do not require 510 (k) clearance, PMA ~~approval~~, approval of a Biologics License Application, or BLA, or other premarket authorization from FDA before marketing. We believe our HCT / Ps are regulated solely under Section 361 of the PHSA, and therefore, we have not sought or obtained 510 (k) clearance, PMA ~~approval~~, or licensure through a BLA for such HCT / Ps. The FDA could disagree with our determination that these human tissue products are Section 361 HCT / Ps and could determine that these products are orthobiologics requiring a BLA or medical devices requiring 510 (k) clearance or PMA ~~approval~~, and could require that we cease marketing such products and / or recall them pending appropriate clearance, ~~approval~~ or licensure from the FDA. If we have to cease marketing and / or have to recall any of our Section 361 HCT / P products, our net sales would decrease, which would adversely affect our business, results of

operations and financial condition. HCT / Ps that do not meet the criteria of Section 361 are regulated under Section 351 of the PHSA. Unlike Section 361 HCT / Ps, HCT / Ps regulated as " 351 " HCT / Ps are subject to premarket review and approval by the FDA. In November 2017, the FDA released a guidance document entitled " Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue — Based Products: Minimal Manipulation and Homologous Use — Guidance for Industry and Food and Drug Administration Staff. " The guidance indicated that the FDA would exercise enforcement discretion, using a risk- based approach, with respect to the IND application and pre- market approval requirements for certain HCT / Ps that it considered to be marketed unlawfully as Section 361 HCT / Ps for a period of 36 months from the issuance date of the guidance to allow manufacturers to pursue submission of an IND application. Under this approach, FDA indicated that high- risk products and uses could be subject to immediate enforcement action. The FDA resumed enforcement of Investigational New Drug Application and premarket approval requirements with respect to these products as of June 1, 2021. In addition, the FDA may in the future modify the scope of its enforcement discretion with respect to Section 361 HCT / Ps or change its position on which current or future products qualify as Section 361 HCT / Ps, or determine that some or all of our HCT / P products may not be lawfully marketed under the FDA' s policy of enforcement discretion. Any regulatory changes could have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring pre- market clearance or approval and compliance with additional post- market regulatory requirements with respect to those products. In the EU, ~~while~~ there is no standalone regulatory framework which applies to products containing human tissues or cells. However ~~,~~, specific requirements are applicable to the donation, procurement, testing, processing, preservation, storage and distribution of such human materials under Directive 2004 / 23 / EC (the EU Tissues and Cells Directive), as implemented in the EU member states, which ~~providesproviding~~ **provides** for general quality and safety requirements applicable to some or all of the abovementioned activities performed in relation to human cells and tissues. Additional requirements set out under other EU regulations and directives, ~~—~~such as the EU Medical Devices Regulation, ~~n —~~may also apply to our human tissues or cells containing products, depending on their characteristics. EU member states national competent authorities may disagree with our determination of which requirements are applicable to our products ~~,~~and may determine that additional requirements are applicable to our products which contain human cells and tissues. Failure to comply with these requirements could jeopardize our ability to sell our products and result in enforcement actions, which could harm our reputation, business, financial condition, results of operations and prospects. In addition, regulatory authorities' policies with respect to human tissues or cells may change and additional government regulations may be enacted. For instance, the regulatory landscape related to human tissues and cells in the EU is evolving. In July 2022, a proposal for a regulation governing substances of human origin was adopted by the European Commission. Such regulatory changes may have adverse consequences for us and make it more difficult or expensive for us to conduct our business in the EEA. Our importer of tissues and cells is based in the UK ~~,~~and is therefore subject to the licensing regime of the UK Human Tissue Authority. Any non- compliance by our importer may have an impact on its licensing status and could have consequential effects on our ability to import and distribute the tissues and cells necessary for certain of our products. Modifications to our marketed medical device products may require new 510 (k) clearances, ~~PMA~~ **PMAs** ~~approvals~~ , or certifications or may require us to cease marketing or recall the modified products until clearances, approvals or certifications are obtained. Modifications to any of our current 510 (k)- cleared products may require new regulatory approvals or clearances, including 510 (k) clearances or PMAs, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510 (k) clearance is necessary. However, the FDA can review a manufacturer' s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and / or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions. If the FDA requires us to go through a lengthier, more rigorous **examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.** 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 PMA application. Where we determine that modifications to our products requires a new 510 (k) clearance or PMA 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. Obtaining clearances and approvals can be a time- consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. In the EU, devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021, may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no substantial change must be made to the device as such a modification would trigger the obligation to obtain a new certification under the EU Medical Devices Regulation and therefore to have a notified body conducting a new conformity assessment of the devices. Once our devices will be certified under the EU Medical Devices Regulation, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the General safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation or cause a substantial change to the intended use for

which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new CE certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. Failure to comply with post- marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market. We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration and listing of devices. For example, medical device manufacturers must submit periodic reports to the FDA as a condition of obtaining marketing authorization. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. In addition, any marketing authorizations we are granted are limited to the authorized indications for use. Further, the manufacturing facilities for a product are subject to periodic review and inspection. Subsequent discovery of problems with a product, manufacturer, or manufacturing facility may result in restrictions on the product, manufacturer or manufacturing facility, withdrawal of the product from the market or other enforcement actions. The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Plus , regulations, such as the FDA and other state and foreign regulatory authorities, have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions: • untitled letters or warning letters; • fines, injunctions, consent decrees and civil penalties; • recalls, termination of distribution, administrative detention or seizure of our products; • customer notifications or repair, replacement or refunds; • operating restrictions or partial suspension or total shutdown of production; • delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations or certifications of new products, new intended uses or modifications to existing products; • withdrawals or suspensions of our current 510 (k) clearances or HDE approval or certifications, resulting in prohibitions on sales of our products; • FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and • criminal prosecution. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. In addition, the FDA may change its clearance policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such changes may also occur in foreign jurisdictions where we market our products. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances, approvals or certifications, increase the costs of compliance or restrict our ability to maintain our clearances or certifications of our current products. In addition, we are required to conduct post- market testing and surveillance to monitor the safety or effectiveness of some of 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 the FDA' s Quality System Regulation (QSR), may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals or certifications, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. Legislative or regulatory reforms may have a material adverse effect on us. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. For example, on February 23, 2022, the FDA issued a proposed rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization, or ISO, standards. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business. Additionally, in September 2019, the FDA issued revised guidance describing an optional " safety and performance based " premarket review pathway for manufacturers of " certain, well- understood device types " to demonstrate substantial equivalence under the 510 (k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list of device types appropriate for the " safety and performance based " pathway and continues to develop product- specific guidance documents that identify the performance criteria for each such device type, as well as the recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510 (k) clearances or otherwise create competition that may negatively affect our business. In addition, FDA and foreign regulations and guidance are often revised or reinterpreted by the FDA and other foreign authorities ~~,~~ in ways that may significantly affect our business and our products. Any new statutes, regulations or

revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance, approval or certification for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing before obtaining clearance, approval or certification; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability. The EU landscape concerning medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted, which repeals and replaces the EU Medical Devices Directive and the Council Directive 90 / 385 / EEC (the EU Active Implantable Medical Devices Directive). Unlike directives, which must be implemented into the national laws of the EU member states, the regulations ~~is~~ **are** directly applicable, i. e., without the need for EU member states to implement into national laws, in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member States. The EU Medical Devices Regulation is also applicable in the EEA. The EU Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. The modifications brought by this new Regulation may have an effect on the way we conduct our business in the EU and the EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed, which could adversely affect our ability to grow our business in a timely manner. In addition, in response to perceived increases in health care costs in recent years there have been and continue to be proposals by the federal government, state governments, regulators and third- party payors to control these costs and, more generally, to reform the U. S. health care system. Certain of these proposals could limit the prices we will be able to charge for our products or the amount of reimbursement available for our products and could limit the acceptance and availability of our products. In March 2010, the federal government enacted the ACA. Among other provisions, the ACA established new value- based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Also, Medicare payments to providers were reduced, effective on April 1, 2013, and will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 **,** through August 15, 2021 **,** for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. There are additional state and federal health care reform measures under consideration that may be adopted in the future which could have a material adverse effect on our industry generally and on our customers. We cannot predict what health care programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any regulatory and legal changes that lower reimbursement for our products, increase taxes on our medical devices, increase cost containment pressures on us or others in the health care sector or reduce medical procedure volumes could adversely affect our business, financial condition, results of operations or cash flows. In the EU, similar developments may affect our ability to profitably commercialize our products, if certified. In December 2021, Regulation No 2021 / 2282 on Health Technology Assessment (HTA) amending Directive 2011 / 24 / EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once the Regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation intends to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. Our products must be manufactured in accordance with federal and state quality regulations and are subject to FDA and foreign inspection, and our failure to comply with these regulations could result in fines, product recalls, product liability claims, limits on future product clearances, reputational damage and other adverse impacts. The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA' s QSR and foreign requirements which are complex regulatory schemes that cover the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA, foreign regulatory authorities and notified bodies enforce the QSR through periodic announced or unannounced inspections or audits of medical device manufacturing facilities, which may include the facilities of subcontractors. We or our

third- party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or foreign regulatory requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: (i) warning letters or untitled letters; (ii) fines, injunctions or civil penalties; (iii) suspension or withdrawal of approvals, clearances or certifications; (iv) customer notifications or repair, replacement, refunds, detention, seizures or recalls of our products; (v) total or partial suspension of production or distribution; (vi) administrative or judicially imposed sanctions; (vii) the FDA' s or foreign authorities or notified body' s refusal to grant pending or future clearances, approvals or certifications for our products; (viii) clinical holds; (ix) refusal to permit the import or export of our products; and (x) criminal prosecution of us or our employees. Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs. The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Except for our total talus spacer, which is authorized for marketing under a HDE, and our orthobiologics such as our PRESERVE Bone Graft System, which are regulated as HCT / Ps, our marketed products are either Class II medical devices cleared by the FDA for specific indications or they are Class I exempt for general orthopaedic use. We have no products that are Class III medical devices. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA or foreign- authorized indications for use, known as " off- label uses. " We cannot, however, prevent a physician from using our devices off- label, when in the physician' s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our devices off- label. Furthermore, the use of our devices for indications other than those cleared, approved or certified by the FDA or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. If the FDA or foreign regulatory authorities determines that our promotional materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. We could face similar consequences from action by foreign regulatory bodies. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government health care programs and the curtailment of our operations. In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management' s attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. Our medical device products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA or foreign regulatory authorities, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA and similar foreign regulations when we receive or become aware of information that reasonably suggests that one or more of our medical device products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or foreign regulatory authorities could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, approval or certification, seizure of our products or delay in clearance, approval or certification of future products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new clearances, approvals, or certifications for the device before we may market or distribute the corrected device. Seeking such clearances, approvals, or certifications may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA or foreign regulatory authorities warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign authorities. We may initiate voluntary withdrawals or corrections for our products in the

future that we determine do not require notification of the FDA or foreign authorities. If the FDA or foreign authorities disagree with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. In addition, we have had in the past, and may in the future, reports of adverse events associated with our products and procedures. While inherent in the medical device and surgical industry, frequent adverse events can lead to reputational harm and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. Disruptions at the FDA, other government agencies and notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA, foreign regulatory authorities and notified bodies to review and clear, approve, or certify new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA' s or other bodies' ability to hire and retain key personnel and accept the payment of user fees and other events that may otherwise affect the FDA' s or other bodies' ability to perform routine functions. Average review times at the FDA or other bodies' have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for medical devices or modifications to cleared or authorized medical devices to be reviewed by necessary government agencies or certified by notified bodies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic, and ~~any~~ **variants and** ~~resurgence~~ **resurgences** of the virus ~~or emergence of new variants~~ may lead to further inspectional delays. Regulatory authorities outside the United States have adopted or may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA, other regulatory authorities or notified bodies from conducting their regular inspections, audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, other regulatory authorities and notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on business. In the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. While several notified bodies have been designated, the COVID- 19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests for (re) certification under the new Regulation as a consequence of which review times have lengthened. This situation could impact our ability to grow our business in the EU and EEA. The clinical study process is lengthy and expensive with uncertain outcomes, and the results of earlier studies may not be predictive of future clinical trial or clinical study results ~~,~~ or provide favorable safety or efficacy data for our products. We cannot guarantee our on- going post- market clinical studies, or any other clinical study we may conduct or sponsor in the future, will be successful, and such clinical studies could be lengthy and expensive to conduct. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. Clinical studies must be conducted in accordance with the laws and regulations of the FDA, other applicable regulatory authorities' and foreign authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and institutional review board or other reviewing bodies at the medical institutions where the clinical studies are conducted. Furthermore, we rely, and in the future may continue to rely upon, on contract research organizations (CROs), and clinical study sites to ensure the proper and timely conduct of our clinical studies and while we have agreements governing their committed activities, we have limited influence over their actual performance. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study to required good clinical practice standards or are delayed for a significant time in the execution of studies, including achieving full enrollment, we may be affected by increased costs, program delays or both. The initiation and completion of any of clinical studies may be prevented, delayed or halted for numerous reasons, which could adversely affect the costs, timing or successful completion of our clinical studies. In addition, disruptions caused by the COVID- 19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical studies. Any of these occurrences may significantly harm our business, financial condition and prospects. Furthermore, patient enrollment in clinical studies and completion of patient follow- up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. If the third parties on which we rely to conduct our clinical studies and to assist us with pre- clinical development do not perform as required or expected, we may not be able to obtain regulatory clearance, approval or certification for or commercialize our products. We may not have the ability to independently conduct our pre- clinical and clinical studies for our future products and we may need to rely on third parties, such as CROs, medical institutions, collaborators, clinical investigators and contract laboratories to conduct such trials. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third

parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of study sponsors, principal investigators and study sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities or other bodies may require us to perform additional clinical studies before clearing or approving our marketing applications or certifying our products. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our future clinical studies or clinical trials comply with the GCP regulations. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID- 19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre- clinical development activities or clinical studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval or certification for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations and financial condition. In the course of our operations, we may collect, use, store, disclose, transfer and otherwise process an increasing volume of personal information, including from our employees and third parties with whom we conduct business. We and our partners may be subject to federal, state and foreign data protection laws and regulations (i. e., laws and regulations that address data privacy and security). In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws and consumer protection laws and regulations (e. g., Section 5 of the FTC Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our partners. We may also be subject to U. S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA- covered entity or business associate in a manner that is not authorized or permitted by HIPAA. The regulatory framework for data privacy and security worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. Certain states have also adopted comparable privacy and security laws and regulations that govern the privacy, processing and protection of health- related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, California enacted the California Consumer Privacy Act (CCPA) on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (CPRA), generally went into effect on January 1, 2023, and significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It has also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. In the EU, the European Union General Data Protection Regulation (GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the European Union (CJEU) limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU- US Privacy Shield Framework for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses (SCCs). In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU- US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022, on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020, have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and / or

start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Relatedly, following the UK' s withdrawal from the EEA and the EU, and the expiry of the transition period, from January 1, 2021, companies have had to comply with both the GDPR and the GDPR as incorporated into UK national law, the latter regime having the ability to separately fine up to the greater of £ 17. 5 million or 4 % of global turnover. If we do not comply with our obligations under the GDPR and the UK data protection laws, we could be exposed to the fines discussed above. In addition, we may be the subject of litigation and / or adverse publicity, which could adversely affect our business, results of operations and financial condition. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self- regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations. Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation and adversely affect our business and results of operations. In addition, if our practices are not consistent, or viewed as not consistent, with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and results of operations. Risks Related to Ownership of Our Common Stock The market price of our common stock may fluctuate substantially or may decline regardless of our operating performance, which could result in the loss of part or all of your investment. The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including: • Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates; • delays or setbacks in the ongoing commercialization of our foot and ankle products and procedures; • the success of existing or new competitive products or technologies; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the commencement of litigation; • actual or anticipated changes in estimates as to financial condition and results of operations; • announcement or expectation of additional financing efforts; • announcements by us or our competitors of significant business developments, acquisitions, new offerings, licenses, strategic partnerships, joint ventures or capital commitments; • the impact of COVID- 19 or other pandemics on the performance of elective procedures; • the impact of political instability, natural disasters, events of terrorism and or war, such as the war between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China **, and the conflict in the Middle East, (including recent attacks on merchant ships in the Red Sea)** ; • sales of our common stock by us, our insiders or other stockholders; • expiration of market standoff or lock- up agreements; • variations in our financial results or those of companies that are perceived to be similar to us; • various macroeconomic events, including changes in inflation, interest rates and overall economic conditions and uncertainties; • changes in the structure of health care payment systems; • market conditions in the medical device sectors; • changes in the anticipated future size and growth rate of our market; • the seasonality of our business; • an increase in the rate of returns of our products or an increase in warranty claims; • general economic, industry and market conditions, including economic recessions or slowdowns; and • the other factors described in this " Risk Factors " section. In recent years, the stock market in general, and the market for medical device companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Further, the stock market in general has been highly volatile due to various macroeconomic events. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company' s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management' s attention and resources from our business. If our operating and financial performance in any given period does not meet any guidance that we provide to the public, the market price of our common stock may decline. We have provided public guidance on our expected operating and financial results for future periods. Such guidance will be comprised of forward- looking statements subject to the risks and uncertainties described in this Annual Report on Form 10- K and in our other public filings and public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. If, in the future, our operating or financial results for a particular period

do not meet any guidance we provide or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of our common stock may decline. Even if we do issue public guidance, there can be no assurance that we will continue to do so in the future. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, our management is required to report upon the effectiveness of our internal control over financial reporting. ~~Once~~ **Now that** we are no longer an emerging growth company, our independent registered public accounting firm **is** ~~will be~~ required to attest to the effectiveness of our internal control over financial reporting ~~as well~~. The rules governing the standards that must be met in assessing our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. In connection with our evaluation of our internal control over financial reporting, we may need to upgrade our systems, including information technology; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. 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. In addition, any testing by us or our independent registered public accounting firm conducted in connection with Section 404 of the Sarbanes- Oxley Act of 2002 may reveal 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 or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third- party litigation, as well as investigations by the SEC, the stock exchange on which our securities are listed, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies. As discussed in Part II, Item 9A of this Annual Report on Form 10- K, we previously identified **disclosed an immaterial error associated with our Zions Facility related to the recognition and disclosure of an interest rate swap agreement in prior reporting periods, which was an indication that a** material ~~weaknesses~~ -- **weakness** ~~in~~ **existed within our internal controls. During the quarter ended December 31, 2023, our management identified and implemented changes to** our internal control over financial reporting ~~related to to the fact that we did not design or maintain an effective control environment, with the primary contributing factor being lack of adequate controls related to manual journal entries and lack of formal accounting policies, processes and controls to analyze, account for and disclose complex transactions. During the year ended December 31, 2022, our management identified and implemented changes to our internal control over financial reporting~~ to remediate the deficiencies that led to the **indication of** material weakness, and, as a result of such changes, our management concluded that the **indication of** material weaknesses had been remediated and that our internal control over financial reporting was effective as of December 31, ~~2022~~ **2023**. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will prevent or avoid **any** potential future material ~~weaknesses~~ -- **weakness**. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the NYSE or other adverse consequences that would materially harm ~~to~~ our business. If securities analysts do not publish research or reports about our business or if they publish negative or inaccurate research about our business, our common stock price and trading volume could decline. Our stock price and trading volume will be influenced by the way analysts and investors interpret our financial information and other disclosures. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline. Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the appreciation in the price of our stock. We have never paid cash dividends and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects for future earnings and other factors our board of directors may deem relevant. In addition, our loan agreements ~~limits~~ -- **limit** our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you then sell our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it. In addition, our loan agreements limit our ability to pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. Future sales and issuances of our capital stock or rights to purchase capital stock could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline. We may issue additional securities. Future sales and issuances of our capital stock or rights to purchase our capital stock could result in dilution to our existing stockholders. We may sell common stock, convertible securities, and other equity securities in one or more transactions at prices and in a manner as we may determine from time to time to fund operations, develop new products, accelerate other strategies, make acquisitions or support other activities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future

offerings. If we sell any such securities in subsequent transactions, investors may be materially diluted. New investors to such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock. Insiders have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control. As of December 31, ~~2022~~ **2023** , our directors, officers, **and** certain **of** ~~stockholders and~~ their respective affiliates owned a ~~majority~~ **substantial portion** of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock. Anti- takeover provisions in our ~~third~~ amended and restated certificate of incorporation **, as amended** and **second** amended and restated bylaws, and Delaware law, could discourage a change in control of our company or a change in our management. Our ~~third~~ amended and restated certificate of incorporation **, as amended (the" Certificate of Incorporation")** and **second amended and restated** bylaws contain provisions that might enable our management to resist a takeover. These provisions include: • a classified board of directors **, until the 2028 annual meeting of the stockholders** ; • advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice; • a supermajority stockholder vote requirement for amending certain provisions of our **Certificate of Incorporation and second** amended and restated ~~certificate of incorporation and~~ bylaws **until the 2028 annual meeting of the stockholders and then a simple majority vote thereafter** ; • the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer; • allowing a supermajority of stockholders to remove directors only for cause **until the 2028 annual meeting of the stockholders and then a simple majority vote thereafter** ; • a requirement that the authorized number of directors may be changed only by resolution of the board of directors; • allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law; • eliminate cumulative voting in elections of directors; • a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent; • limiting the forum to Delaware for certain litigation against us; and • limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president, in the absence of a chief executive officer. These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the DGCL), which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any " interested " stockholder for a period of three years following the date on which the stockholder became an " interested " stockholder. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. Our ~~third amended and restated certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** and **second** amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that: • We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person' s conduct was unlawful. • We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law. • We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification. • We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification. • The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. • We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents. Our ~~third amended and restated certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** and **second** amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our ~~third amended and restated certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** and **second** amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our ~~third amended and restated certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** ~~or our~~ **or our second** amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our ~~third amended and restated certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** and **second** amended and restated bylaws also provide that the federal district courts of the United States of

America are the exclusive forum for the resolution of any complaint asserting a cause of action against any defendant arising under the Securities Act. Such provisions are intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any of this Annual Report on Form 10- K. The choice of forum provisions do not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find one or more of the choice of forum provisions that are contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could seriously harm our business. General Risk Factors Unfavorable global and regional economic, political and health conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by global or regional economic, political and health conditions. A global financial crisis or global or regional political and economic instability (including changes in inflation, interest rates and overall economic conditions and uncertainties), wars, terrorism, civil unrest, outbreaks of disease (for example, COVID- 19), and other unexpected events, such as supply chain constraints or disruptions, could cause extreme volatility, increase our costs and disrupt our business. Business disruptions could include, among others, disruptions to our commercial activities, including due to supply chain or distribution constraints or challenges, clinical enrollment, clinical site availability, patient accessibility and conduct of our clinical trials, as well as temporary closures of our facilities and the facilities of suppliers or contract manufacturers in our supply chain. For example, these macroeconomic factors could affect the ability of our current or potential future manufacturers, sole source or single source suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply components, materials or services relevant to our products. Any failure by any of them to remain in business could affect our ability to manufacture products or meet demand for our products. In addition, if inflation or other factors were to significantly increase our business costs, we may be unable to pass through price increases to our customers. Interest rates and the ability to access credit markets could also adversely affect the ability of our customers to purchase our products. In addition, during certain crises and events, patients may prioritize other items over certain or all of their treatments and / or medications, which could have a negative impact on our commercial sales. The COVID- 19 outbreak, including developments involving subsequent COVID- 19 variants, significantly affected the financial markets of many countries and resulted **in** and may in the future result in a variety of federal, state and local orders, guidance and restrictions. We cannot, at this time, predict the specific extent, duration, or full impact that the COVID- 19 outbreak will have on our ongoing and planned clinical trials and other business operations, including our commercialization activities. To the extent the COVID- 19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this" Risk Factors" section. Also, as a result of the current geopolitical tensions and conflict between Russia and Ukraine, and the recent invasion by Russia of Ukraine, the governments of the United States, EU, Japan and other jurisdictions have recently announced the imposition of sanctions on certain industry sectors and parties in Russia and certain impacted regions, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the global supply chain, with negative implications on the availability and prices of raw materials and components, as well as the on global financial markets and financial services industry. A severe or prolonged economic downturn, political disruption or adverse health conditions could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business. Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control. A major hurricane, fire or other disaster (such as a major flood, earthquake or terrorist attack) affecting our headquarters or our other facilities, or facilities of our suppliers and manufacturers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our suppliers' and manufacturers' damaged facilities, which delays could be lengthy and costly. **Our** ~~We opened a new~~ headquarters facility in Englewood, Colorado, ~~to support~~ **supports** our commercial expansion, education and training programs. Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. If any of our customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, effects of the disaster could create some uncertainty in the operations of our business. 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 manufacturers and our customers. Litigation against us could be costly and time-consuming to defend and could result in additional liabilities. We may from time to time be subject to legal proceedings and

claims that arise in the ordinary course of business or otherwise, such as claims brought by our customers in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients or vendors of our customers, or stockholders. Further, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, and this risk is especially relevant to industries that experience significant stock price volatility. Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management' s attention and resources, which may negatively affect our business, financial condition and results of operations ~~. The requirements of being a public company may divert our management' s attention from our growth strategies and other business concerns. As a public company, we are subject to the reporting requirements of the Exchange Act and are required to comply with the applicable requirements of the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of the NYSE and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. Among other things, the Exchange Act requires that we file annual, quarterly and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal controls over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management' s attention may be diverted from executing our growth strategies and managing other business concerns and, which could have a material adverse effect on our business, financial condition and results of operations. Although we have hired additional employees to comply with these requirements, we may need to hire even more employees in the future, which will increase our costs and expenses. Additionally, as a public company, it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers. We incur significant costs as a result of operating as a public company and our executive management team devotes substantial time to public company compliance programs. As a public company, we incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes- Oxley Act, as well as rules implemented by the SEC and the NYSE. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our executive management team and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd- Frank Wall Street Reform and Consumer Protection Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations may cause us to incur significant legal and financial compliance costs and may make some activities more time- consuming and costly ~~. We are subject to U. S. anti- bribery, anti- corruption, and anti- money laundering laws, including the U. S. Foreign Corrupt Practices Act, as well as export control, customs laws sanctions and other trade laws and regulations (collectively, the Trade Laws). We can face serious consequences for violations. As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U. S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U. S. Foreign Corrupt Practices Act (FCPA), and other federal statutes and regulations, including those established by the Office of Foreign Assets Control (OFAC). In addition, the UK Bribery Act of 2010 (Bribery Act) prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented adequate procedures to prevent bribery. These anti- corruption laws generally prohibit companies and their employees, agents and intermediaries from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. We are also subject to other U. S. laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Likewise, any investigation of potential violations of Trade Laws could also have an adverse impact on our reputation, our business, results of operations and financial condition. We cannot assure you that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti- corruption, anti- money laundering and anti- terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, financial condition and results of operations. We, along with our suppliers, are dependent on various information technology systems, and failures of, interruptions to, or unauthorized tampering of those systems could have a

material adverse effect on our business. We and our suppliers rely extensively on information technology systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security system and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided or used by third- parties or their vendors, to conduct business. These systems include, but are not limited to, ordering and managing materials from suppliers, converting materials to finished products (suppliers), shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, providing data security and other processes necessary to manage our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The use of cloud- based computing creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third- party providers' systems, portable media or storage devices. Despite the implementation of security measures, our information technology systems and those of our contractors, consultants and collaborators have been and are vulnerable to damage from cyberattacks, " phishing " attacks, intentional or accidental actions or omissions to act that cause vulnerabilities, computer viruses and malware, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID- 19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate timely, we may suffer interruptions in our ability to manage operations, and would also be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, financial condition, results of operations and prospects. We cannot assure you that any limitations of liability provisions in our contracts would be enforceable or adequate or would otherwise protect us from any liabilities or damages with respect to any particular claim relating to a security lapse or breach. While we maintain certain insurance coverage, including cyber insurance, our insurance may be insufficient or may not cover all liabilities incurred by such attacks. We also cannot be certain that our insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceeds available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation. Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. We presently have general liability, workers' compensation, directors' and officers' and product liability insurance coverage, which is subject to deductibles and coverage limitations. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could negatively affect our business, financial condition and results of operations. We do not carry specific hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical studies, clinical trials or regulatory approvals could be suspended. ~~Additionally, we do not carry cyber insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources. We also expect that operating~~ **Operating** as a public company ~~will make~~ **makes** it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the **desired** ~~same or similar~~ coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations. Our results may be impacted by changes in foreign currency exchange rates. A significant proportion of our sales are outside of the United States, and a majority of those are denominated in foreign currencies, which exposes us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful, and our business could be harmed. Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them. Our products may be subject to U. S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, will harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of

our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U. S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U. S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely negatively affect our business, financial condition and results of operations. Changes in tax laws or regulations that are applied adversely to us or our customers may seriously harm our business. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us, possibly on a retroactive basis. Our ability to use net operating losses to offset future taxable income may be subject to certain limitations. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " generally defined as a cumulative change of more than 50 percent (by value) in its equity ownership by certain stockholders over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards (the NOLs) and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. We may have experienced ownership changes in the past, and we may experience ownership changes as a result of future shifts in our equity ownership, some of which may be outside our control. As a result, our ability to use our pre- change federal NOLs and other tax attributes to offset future taxable income and taxes could be subject to limitations. For these reasons, we may not be able to utilize a material portion of the NOLs, even if we achieve profitability, which could adversely affect our business, financial condition and cash flows. As international expansion of our business occurs, it will expose us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. Our long- term strategy is to increase our international presence. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international payers. Doing business internationally involves a number of risks, including: • difficulties in staffing and managing our international operations; • increased competition as a result of more products and procedures receiving regulatory approval or otherwise free to market in international markets; • export restrictions, trade regulations and foreign tax laws; • fluctuations in currency exchange rates; • difficulties in developing effective marketing campaigns in unfamiliar foreign countries; • multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • reduced or varied protection for intellectual property rights in some countries; • obtaining foreign certification and regulatory clearance where required in various countries; • requirements to maintain data and the processing of that data on servers located within such countries; • complexities associated with managing multiple payer reimbursement regimes, government payers or patient self- pay systems; • customs clearance and shipping delays; • limits on our ability to penetrate international markets if there is a preference for locally produced products or if we are required to manufacture our products locally; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value- added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • restrictions on the site- of- service for use of our products and the economics related thereto for physicians, providers and payers; • natural disasters, political and economic instability, including wars such as the war between Ukraine and Russia as well as any sanctions or other actions resulting therefrom, terrorism, political unrest, outbreak of disease (including the impact of the COVID- 19 pandemic), boycotts, curtailment of trade and other market restrictions; and • regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U. K. Bribery Act of 2010 and comparable laws and regulations in other countries. Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations. Our business could be negatively impacted by corporate citizenship and ESG matters and / or our reporting of such matters. Institutional, individual, and other investors, proxy advisory services, regulatory authorities, consumers and other stakeholders are increasingly focused on environmental, social and governance, or ESG, practices of companies. As we look to respond to evolving standards for identifying, measuring, and reporting ESG metrics, our efforts may result in a significant increase in costs and may nevertheless not meet investor or other stakeholder expectations and evolving standards or regulatory requirements, which may negatively impact our financial results, our reputation, our ability to attract or retain employees, our attractiveness as a service provider, investment, or business partner, or expose us to government enforcement actions, private litigation, and actions by stockholders or stakeholders.