Risk Factors Comparison 2024-03-05 to 2023-03-06 Form: 10-K

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In addition to the other information contained in this Annual Report and the exhibits hereto, you should carefully consider the risks described below. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. This Annual Report also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below or elsewhere in this Annual Report. Investing in our common stock involves a high degree of risk and if any of these risks or uncertainties occur, the trading price of our common stock could decline and you could lose part or all of your investment. The disclosures in this Item 1A of this Annual Report under the heading " Risk Factors " relate to the combined company subsequent to the merger unless otherwise noted. Summary of Risk Factors The section provides a summary of many of the risks we are exposed to in the normal course of our business activities. The summary does not contain all of the information that may be important to you, and you should read the summary together with the more detailed discussion of risks set forth following this section as well as elsewhere in this report. • ~~The merger of Orthofix and SeaSpine may trigger change in control or other provisions in certain distributor, customer and other agreements, any of which may have an adverse impact on the combined company' s business and results of operations. • Uncertainties associated with the merger may cause a loss of management personnel and other key employees. • Stockholder litigation related to the merger could negatively affect our business and operations. •~~ Integration of the Orthofix and SeaSpine businesses is expected to be expensive and time- intensive and we may not be able to successfully integrate the businesses and / or realize anticipated synergies and benefits in a timely manner, if at all. • We are subject to a wide range of requirements, regulations, and laws due to our international operations and related to the medical device industry in which we operate, the violation of any of which could subject us to adverse consequences. • Ongoing healthcare reform initiatives and changes in third- party reimbursement policies and in the healthcare industry aimed at cost containment may adversely impact our business. • We and certain of our suppliers are subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products. • Oversight of the medical device industry might affect the way we sell medical devices and compete in the marketplace. • ~~An~~ **A** FDA panel recommended that bone growth stimulator devices be reclassified by the FDA from Class III to Class II devices, which could increase future competition for us in this product category and negatively affect our future sales of such products. • We are subject to requirements relating to hazardous materials which may impose significant compliance or other costs on us. • The COVID- 19 pandemic **or other such global events** , and the related effects thereof, ~~has materially adversely affected, and~~ could ~~continue to~~ materially adversely affect, our operations, supply chain, manufacturing, product demand, product distribution, customers **,** and other business activities ~~. • The ongoing conflict between Russia and Ukraine, and the global response to it, could adversely impact our global operations~~ . • Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a ~~group purchasing organization (" GPO ")~~ or similar entity excludes us from being a supplier. • The industry in which we operate is highly competitive. New product developments and improvements by our competitors could make our products or technologies non- competitive or obsolete. Similarly, unless clinical studies demonstrate the safety and efficacy of our products, alone and relative to competitive products, our sales may be adversely affected. • Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third parties, including physicians, hospitals, and third **-** party payors. • Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully complete clinical trials and obtain regulatory approval for our product candidates on our anticipated timelines at reasonable costs to us, or at all, could have a material adverse effect on our business, operating results **,** and financial condition. • If the third parties on which we rely to conduct our clinical studies do not perform as contractually required or expected, we may not obtain required approvals for or commercialize our products ~~. • Certain of our products are derived from human tissue or contain materials derived from animal sources and are or could be subject to additional regulations~~ . • Unfavorable negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our products. • We may not be able to successfully introduce new products to the market and, if we do, market acceptance or the market size for our products may not be as we expect. • There is no guarantee that regulatory authorities, U. S. or foreign, will grant clearance or premarket approval of our future products. • Our success depends on our ability to successfully educate and train surgeons and their staff on the benefits, safety, cost- effectiveness, and proper use of our products. • Security breaches, cyber- attacks, loss of data, and other disruptions to our information technology systems could compromise sensitive information and / or adversely affect our business. • Our business could be harmed if any of our manufacturing, development **,** or research facilities are damaged and / or our manufacturing processes are interrupted. • We depend on a limited number of third- party manufacturers and suppliers for manufacturing and processing activities, components, and raw materials. Failure of these third parties to perform as expected could result in substantial delays, increased costs or failures of our product development programs, or delayed or unsuccessful commercialization of our products. • We may not maintain or grow our revenue if we are unable to maintain and expand our network of independent sales representatives and distributors. • Our success depends on the services of key members of our senior management and other key employees. • Our business is subject to economic, political, regulatory, and other risks associated with international sales and operations. • Our failure to adequately protect or enforce our intellectual property rights could harm our position in the marketplace or prevent or impede the commercial protection of our products. • We

may be subject to third parties claims for infringement or misappropriation of their intellectual property. • There have been substantial intellectual property disputes in our industry, which are inherently costly, divert significant time and other resources, and have unpredictable outcomes. • We may have significant product or other liability exposure, some of which may not be covered by insurance, and if covered by insurance, such coverage may not cover all claims, which could require us to pay substantial sums. • Our efforts to identify, pursue, and implement new business opportunities (including acquisitions) may be unsuccessful. • We have invested in and provided loans to privately- held companies and if they are unsuccessful, we may lose all of our investment and our loans may not be repaid. • Our sales volumes and our operating results may fluctuate. • Our goodwill, intangible assets **,** and fixed assets are subject to potential impairment which could adversely affect our future financial results. • We maintain a $ ~~300~~ **150** . 0 million **financing agreement** ~~secured revolving credit facility~~ secured by a pledge of substantially all of our property. Our failure to comply with the facility' s covenants could result in an event of default, which could adversely affect our future. • We must maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows. • Our future capital needs are uncertain and we may need to raise additional funds in the future, and such funds may not be available on acceptable terms or at all. • Our business could be negatively impacted by corporate citizenship and environmental, social, and governance (" ESG") matters and / or our reporting of such matters. Risks Related to our ~~Recently Completed~~ Merger with SeaSpine The ~~merger may trigger change in control or other provisions in certain distributor, customer and other agreements to which Orthofix or SeaSpine is a party, which may have an adverse impact on the~~ combined company ~~' s~~ **may be unable to successfully integrate the Orthofix and SeaSpine** ~~business~~ **businesses** and **realize the anticipated benefits** ~~results of operations following completion~~ of the merger. The ~~merger may trigger change in control and other provisions in certain agreements to which Orthofix or SeaSpine is a party. If Orthofix or SeaSpine is unable to negotiate waivers of those provisions, counterparties may exercise their rights and remedies under the agreements, including terminating the agreements or seeking monetary damages or equitable remedies. Even if Orthofix and SeaSpine are able to negotiate consents or waivers, the counterparties may require a fee for such waivers or seek to renegotiate the agreements on terms less favorable to Orthofix or SeaSpine. Any of the foregoing or similar developments may have an adverse impact on the combined company' s business and results of operations following the completion of the merger. Uncertainties associated with the merger may cause a loss of management personnel and other key employees, which could adversely affect the future business and operations of the combined company following completion of the merger. We are dependent on the experience and industry knowledge of our officers and other key employees to execute our business plans. The combined company' s~~ success ~~after the completion~~ of the merger will depend **,** in part ~~upon the~~ **, on our** ability ~~of the combined company to retain certain key management personnel and employees of Orthofix and SeaSpine. As a result of the merger, current and prospective employees may experience uncertainty about their roles following the completion of the transactions, which may have an adverse effect on our ability to attract or retain key management and other key personnel. In addition, no assurance can be given that the combined company will be able to attract or retain key management personnel and other key employees to the same extent that Orthofix and SeaSpine have previously been able to attract or retain their own employees. Stockholder litigation could negatively affect our business and operations. On each of November 17, 2022, November 21, 2022, and December 13, 2022, purported then- stockholders of SeaSpine filed a complaint against SeaSpine and the then- members of SeaSpine' s board of directors in the United States District Court for the Southern District of New York and in the United States District Court for the District of Delaware. In addition, on December 13, 2022, a purported then- stockholder of Orthofix filed a complaint against Orthofix and the then- members of Orthofix' s board of directors in the United States District Court for the Southern District of New York. The complaints assert claims under Section 14 (a) of the Exchange Act and Rule 14a- 9 promulgated thereunder and Section 20 (a) of the Exchange Act for allegedly causing a materially incomplete and misleading registration statement on Form S- 4 filed with the SEC on November 8, 2022, or for allegedly causing a materially incomplete and misleading Schedule 14A definitive proxy statement filed with the SEC on November 23, 2022. Among other remedies, the plaintiffs sought to enjoin the merger. All four of these actions have now been voluntarily dismissed by the plaintiffs. On November 19, 2022, counsel to two different purported then- stockholders of SeaSpine sent demand letters making similar assertions. On November 23, 2022, counsel to another purported then- stockholder of SeaSpine sent a draft federal court complaint containing similar allegations, making similar claims under Section 14 (a) of the Exchange Act and Rule 14a- 9 promulgated thereunder and Section 20 (a) of the Exchange Act, and also seeking to enjoin the merger. In addition, on November 15, 2022 and December 20, 2022, counsel to two different purported then- stockholders of Orthofix sent demand letters to Orthofix' s counsel attaching draft federal court complaints against Orthofix and the then- members of the Orthofix board making similar claims under Section 14 (a) of the Exchange Act and Rule 14a- 9 promulgated thereunder and Section 20 (a) of the Exchange Act, and also sought to enjoin the merger. On December 14, 2022, and December 22, 2022, counsel to two additional purported then- stockholders of Orthofix sent demand letters to Orthofix' s counsel containing similar allegations. Although the ultimate outcome of these lawsuits cannot be predicted with certainty, Orthofix and SeaSpine believe the claims are without merit and intend to defend against these actions vigorously. Securities class action lawsuits and derivative lawsuits are often brought against companies that have entered into merger agreements. Additional lawsuits against Orthofix, SeaSpine, Merger Sub and / or the directors and officers of Orthofix and / or SeaSpine in connection with the merger may be filed in the future. Neither Orthofix nor SeaSpine can give assurance as to the outcome of any lawsuit that has been or may be filed, including the amount of costs associated with defending claims or any other liabilities that may be incurred in connection with such litigation. Whether or not any plaintiff' s claim is successful, this type of litigation may result in significant costs and divert management' s attention and resources, which could adversely affect the operation of Orthofix' s and SeaSpine' s business. The combined company may be unable~~ to successfully **combine and** integrate the Orthofix and SeaSpine businesses **,** and realize the anticipated benefits ~~of the merger. The success of the merger will depend, in part, on the combined company' s ability to successfully combine and integrate the Orthofix and SeaSpine businesses, and realize the anticipated benefits~~ , including synergies, cost savings, innovation and

technological opportunities , and operational efficiencies from the merger in a manner that does not materially disrupt existing customer, supplier, and employee relations and does not result in decreased revenues due to losses of, or decreases in orders by, customers. If **we are** ~~the combined company is~~ unable to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits may not be realized fully or at all, or may take longer to realize than expected, and the value of **our** ~~the combined company~~ common stock may decline. Integration may result in additional and unforeseen expenses, and **we** ~~the combined company~~ may fail to realize some or all of the anticipated benefits of the merger on a timely basis or at all. While we have successfully completed a number of integration activities since the closing of merger, the remainder of our integration activities may not be completed smoothly or successfully. The integration of the two companies may result in material challenges, including, without limitation: • managing a larger, more complex combined medical device business; • maintaining employee morale and retaining key management and other employees; • retaining existing business and operational relationships, including customers, suppliers , and employees and other counterparties, as may be impacted by contracts containing consent and / or other provisions that may be triggered by the merger, and attracting new business and operational relationships; • unanticipated issues in integrating the numerous systems involved in operating our businesses, including information technology, communications, purchasing, accounting , and finance, including integrating different accounting policies, sales, billing, payroll, employee benefits, regulatory compliance , and other systems; • successfully addressing inconsistencies in standards, controls, procedures , or policies that could affect our ability to maintain relationships with customers and employees or to achieve the anticipated benefits of the merger; • consolidating corporate and administrative infrastructures and eliminating duplicative operations; • coordinating geographically separate organizations, systems, and facilities and addressing possible differences in business backgrounds, corporate cultures, and management philosophies; and • unforeseen expenses or delays associated with the merger. Many of these factors will be outside of our control, and any one of them could result in delays, increased costs, decreases in the amount of expected revenues , and other adverse impacts, which could materially affect **our** ~~the combined company' s~~ financial position, results of operations , and cash flows. In addition, the integration of certain operations requires the dedication of significant management resources, which may temporarily distract management' s attention from our day- to- day business. Employee uncertainty and lack of focus during the integration process may also disrupt our business. **Our** ~~In addition, SeaSpine completed its merger with 7D Surgical, Inc. in May 2021, and the integration of the SeaSpine business and 7D Surgical remains in process and remains subject to certain risks, including that (a) the benefits expected to be received from the acquisition may not be realized in their entirety, (b) there could be unanticipated adverse impacts on our or 7D Surgical' s business, and / or we may otherwise not realize the expected return on our investment, (c) we may be subject to claims or liabilities related to 7D Surgical' s business arising after the merger was completed and SeaSpine may have failed to identify or assess the magnitude of certain liabilities, shortcomings or other circumstances prior to acquiring 7D Surgical; and (d) 7D Surgical was not required to maintain an internal control infrastructure that would meet the standards of a U. S. public company, and we may incur substantial costs to implement such controls and procedures and we could encounter unexpected delays and challenges in this implementation. The ongoing integration of 7D Surgical may increase the complexity of, and challenges associated with, the integration of the Orthofix and SeaSpine businesses, which may make it more difficult for Orthofix and SeaSpine to achieve the anticipated benefits of the merger fully or at all, or within the anticipated time frame. The~~ future results ~~of the combined company~~ may be adversely impacted if **we do** ~~the combined company does~~ not effectively manage ~~its~~ **our** complex operations following the completion of the merger. Following the ~~completion of the~~ merger, the size of **our** ~~the combined company' s~~ business ~~will be~~ **has become** significantly larger ~~than the current size of either SeaSpine' s business or Orthofix' s business~~ . **Our** ~~The combined company' s~~ ability to successfully manage this expanded business will depend, in part, upon **our** ~~management' s~~ ability to design and implement strategic initiatives that address not only the integration of the Orthofix and SeaSpine businesses, but also the increased scale and scope of the combined business with its associated increased costs and complexity. There can be no assurances that **we** ~~the combined company~~ will be successful in integrating the businesses or that ~~it~~ **we** will realize the expected operating efficiencies, cost savings , and other benefits ~~currently~~ **as originally** anticipated from the merger. We **have** ~~expect to incur~~ **incurred** substantial expenses related to the ~~completion of the~~ merger and **we expect to incur substantial additional expenses related to** the integration of the Orthofix and SeaSpine businesses. We ~~will incur~~ **incurred** substantial expenses in connection with the completion of the merger **and we have incurred substantial expenses related to integration activities performed to date in order** to integrate a large number of processes, policies, procedures, operations, technologies , and systems of Orthofix and SeaSpine ~~in connection~~ **. These activities remain ongoing for certain integration areas, thus we expect to continue to still incur significant expenses associated** with ~~the~~ **these** ~~merger~~ **activities in the future** . The substantial majority of these costs ~~will~~ **are believed to** be non- recurring expenses related to the ~~transactions~~ **transaction** ~~and~~ **, our** facilities **, our personnel,** and systems consolidation costs. **We** ~~The combined company~~ may incur additional costs or suffer loss of business under third- party contracts that are terminated or that contain change in control or other provisions that may be triggered by the completion of the ~~transactions~~ **merger** , and / or losses of, or decreases in orders by, customers, and may also incur costs to **(i)** retain certain key management personnel and employees ~~. Orthofix and SeaSpine will also incur transaction fees and costs related to formulating integration plans for~~ **or** ~~the combined business, and the execution of~~ **(ii) associated with restructuring activities following** ~~these~~ **the merger** ~~plans may lead to additional unanticipated costs and time delays~~ . These incremental transaction- related **and integration** costs may exceed the savings the combined company expects to achieve from the elimination of duplicative costs and the realization of other efficiencies related to the integration of the businesses, particularly in the near term and in the event there are material unanticipated costs. Factors beyond **our** ~~the parties'~~ control could affect the total amount or timing of these expenses, many of which, by their nature, are difficult to estimate accurately ~~. The market price of the combined company common stock after the merger is completed may be affected by factors different from those affecting the price of Orthofix common stock or SeaSpine common stock before the merger is completed. Upon completion of the merger, previous holders of~~

~~Orthofix common stock and previous holders of SeaSpine common stock are now holders of common stock of the combined company. As the businesses of Orthofix and SeaSpine are different, the results of operations, as well as the price of the combined company common stock, may, in the future, be affected by factors different from those factors affecting each of Orthofix and SeaSpine as an independent stand- alone company. The combined company will face additional risks and uncertainties to which each of Orthofix and SeaSpine may not have previously been exposed. As a result, the market price of the combined company' s shares may fluctuate significantly following completion of the merger. The market price of the combined company common stock may decline as a result of the merger, including as a result of some Orthofix and / or SeaSpine stockholders adjusting their portfolios. The market price of the combined company common stock may decline as a result of the merger if, among other things, the operational cost savings estimates in connection with the integration of the Orthofix and SeaSpine businesses are not realized, there are unanticipated negative impacts on Orthofix' s financial position, or if the transaction costs related to the merger are greater than expected. The market price also may decline if the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts or if the effect of the transactions on the combined company' s financial position, results of operations or cash flows is not consistent with the expectations of financial or industry analysts. In addition, sales of combined company common stock after the completion of the merger may cause the market price of such common stock to decrease. Based on the number of shares of SeaSpine common stock outstanding immediately prior to the close of the merger, Orthofix issued an aggregate of approximately 16. 0 million shares of Orthofix common stock to holders of SeaSpine common stock in the merger. Historical SeaSpine stockholders may decide not to hold the shares of combined company common stock they will receive in the merger. In addition, certain Orthofix stockholders, such as funds with limitations on their permitted holdings of stock in individual issuers, may be required to sell their shares of common stock following completion of the merger. Such sales of combined company common stock could have the effect of depressing the market price for the combined company common stock. Any of these events may (i) make it more difficult for the combined company to sell equity or equity- related securities, (ii) dilute your ownership interest in the combined company, and / or (iii) have an adverse impact on the price of the combined company common stock~~ . Risks Related to our Legal and Regulatory Environment If we fail to maintain an effective system of internal controls or discover material weaknesses in our internal control over financial reporting, we may not be able to report our financial results accurately or detect fraud, which could harm our business and the trading price of our common stock. Effective internal controls are necessary for us to produce reliable financial reports and are important in our effort to prevent financial fraud. We are required to periodically evaluate the effectiveness of the design and operation of our internal controls. As has occurred in several years prior, these evaluations may result in the conclusion that enhancements, modifications, or changes to our internal controls are necessary or desirable. While management evaluates the effectiveness of our internal controls on a regular basis, these controls may not always be effective. There are inherent limitations on the effectiveness of internal controls, including collusion, management override, and failure of human judgment. Because of this, control procedures are designed to reduce rather than eliminate business risks. Also, previously effective internal controls may become inadequate over time because of changes in our business or operating structure, and we may fail to take measures to evaluate the adequacy of and update these controls, as necessary. If we fail to maintain an effective system of internal controls or if management or our independent registered public accounting firm were to discover material weaknesses in our internal controls, we may be unable to produce reliable financial reports or prevent fraud, which could harm our financial condition and operating results, and could result in a loss of investor confidence and a decline in our stock price. We **recently identified a material weakness in our internal control over financial reporting, and our business and stock price may be adversely affected if our internal control over financial reporting is not effective. During the financial close for the quarter ended December 31, 2023, we identified a material weakness in our internal controls over financial reporting related to the operation of certain management review controls pertaining to business combinations and goodwill. A more complete description of this material weakness is included in Item 9A," Controls and Procedures" in this Form 10- K. As previously discussed, if we fail to maintain an effective system of internal controls or if management or our independent registered public accounting firm were to discover material weaknesses in our internal controls, we may be unable to produce reliable financial reports or prevent fraud, which could harm our financial condition and operating results, and could result in a loss of investor confidence and a decline in our stock price. We** are subject to the Foreign Corrupt Practices Act (the " FCPA ") and other similar anti- bribery laws and any violations of such laws could subject us to adverse consequences. The FCPA and similar anti- bribery laws in non- U. S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on U. S. publicly traded entities and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Because of the predominance of government- sponsored healthcare systems around the world, many of our customer relationships outside of the U. S. are with governmental entities and are therefore subject to such anti- bribery laws. In recent years, both the U. S. and non- U. S. regulators have increased regulation, enforcement, inspections, and governmental investigations of the medical device industry, including increased U. S. government oversight and enforcement of the FCPA. Despite implementation of a comprehensive global healthcare compliance program, we may be subject to more regulation, enforcement, inspections, and investigations by governmental authorities in the future. Any failure to comply with applicable legal and regulatory obligations in the U. S. or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil, and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, suspension or withdrawal of CE Certificates of Conformity, seizure of shipments, restrictions on certain business activities, disgorgement and other remedial measures, disruptions of our operations, and significant management distraction. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. Any reduction in

international sales, or our failure to further develop our international markets, could have a material adverse effect on our business, results of operations, and financial condition. We are subject to federal and state healthcare fraud, abuse, and anti- self-referral laws, and could face substantial penalties if we are determined not to have fully complied with such laws. Healthcare fraud and abuse regulations by federal and state governments impact our business. Healthcare fraud and abuse laws potentially applicable to our operations include: • The federal Anti- Kickback Statute, which prohibits knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program (such as the Medicare or Medicaid programs); • The federal Stark law, which prohibits physician self- referral, specifically a referral by a physician of a Medicare or Medicaid patient to an entity providing designated health services if the physician or an immediate family member has a financial relationship with that entity; • Federal false claims laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal government payors that are false or fraudulent; and • State and non- U. S. laws analogous to each of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by non- governmental or non- U. S. governmental third-party payors, including commercial insurers. Federal and state government agencies, as well as private whistleblowers, have significantly increased investigations and enforcement activity under these laws. Violations of these laws are punishable by civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, or the exclusion from participation in federal, non- U. S., or state healthcare programs. Although we exercise care in structuring our sales and marketing practices, customer discount arrangements, and interactions with healthcare professionals to comply with these laws and regulations, we cannot provide assurance that government officials will not assert that our practices are not in compliance or that government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation. Even if an investigation is unsuccessful or is not fully pursued, we may spend considerable time and resources defending ourselves and the adverse publicity surrounding any assertion that we may have engaged in violative conduct could have a material and adverse effect on our reputation with existing and potential customers and on our business, financial condition, and results of operations. Reimbursement policies of third parties, cost containment measures, and healthcare reform could adversely affect the demand for our products and limit our ability to sell our products. Maintaining and growing sales of our products depends on the availability of adequate coverage and reimbursement from third- party payors, both within and outside the U. S. Our products are sold either directly by us or by independent sales representatives to customers or to our independent distributors and purchased by hospitals, healthcare providers, and patients. These products may be reimbursed by third- party payors, such as government programs, including Medicare, Medicaid, and Tricare, or private insurance plans, managed care organizations, and healthcare networks. Major third- party payors for medical services in the U. S. and internationally continue to work to contain health care costs, are increasingly challenging the policies and the prices charged for medical products and services, and have or may implement initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments, and managed- care arrangements. Any medical policy developments that eliminate, reduce, or materially modify coverage of our reimbursement rates for our products could have an impact on our ability to sell our products. In addition, third- party payors continually review and revise their coverage and reimbursement policies for procedures involving the use of our products and can, without notice, eliminate or reduce coverage or reimbursement if they determine that a device or product provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder' s healthcare insurance benefits are limited. For example, in the past, a major national third- party insurer in the U. S. reduced coverage (from all or most cases to limited indications) for biomechanical devices (e. g., spine cages) used in cervical fusion procedures, stating that the devices had not been shown to be more effective than bone graft. In addition, certain insurers have limited coverage for vertebral fusions in the lumbar spine and other insurers may adopt similar coverage decisions in the future. Limits put on reimbursement could make it more difficult to buy our products and substantially reduce, or possibly eliminate, patient access to our products. In addition, should governmental authorities continue to enact legislation or adopt regulations that affect third- party coverage and reimbursement, access to our products and coverage by private or public insurers may be reduced with a consequential material adverse effect on our sales and profitability. CMS, in its ongoing implementation of the Medicare program, periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. The impact that this information could have on Medicare coverage policy for our products is currently unknown, ~~but~~ **and** we cannot provide assurances that the resulting actions will not restrict Medicare coverage for our products. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. As required by law, CMS has continued efforts to implement a competitive bidding program for selected DMEPOS items paid for by the Medicare program. In this program, Medicare rates are based on bid amounts for certain products in designated geographic areas, rather than the Medicare fee schedule amount. Bone growth stimulation products are currently exempt from this competitive bidding process. We cannot predict which products from any of our businesses may ultimately be affected or whether or when the competitive bidding process may be extended to our businesses. There can be no assurance that the implementation of the competitive bidding program will not have an adverse impact on the sales of some of our products. With respect to international sales, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country. As in the U. S., our products may not obtain coverage and reimbursement approvals in a timely manner, if at all, in a particular international market. In addition, even if we obtain country- specific coverage and reimbursement approvals, we could incur considerable expense to do so. Our failure to obtain such coverage and approvals would negatively affect market acceptance of our products in the international markets in which such failure occurs and the expenses incurred in connection with obtaining such coverage and approvals could outweigh the benefits of obtaining them.

Globally, our products are sold in many countries, such as the U. K., Germany, France, and Italy, which have publicly funded healthcare systems. The ability of hospitals supported by such systems to purchase our products is dependent, in part, upon public budgetary constraints. Any increase in such constraints may have a material adverse effect on our sales and collection of accounts receivable from such sales. If ~~the trend by~~ governmental agencies and other third- party payors ~~to~~ reduce coverage of and / or reimbursement for procedures using our products ~~continues~~, our business, results of operations, and financial condition could be materially and adversely affected. Further, we cannot be certain that, under current and future payment systems, the cost of our products will be adequately incorporated into the overall cost of the procedure and, accordingly, we cannot be certain that the procedures performed with our products will be reimbursed at a cost- effective level, or at all. We and certain of our suppliers may be subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products. The medical devices we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state, and foreign governmental authorities. These authorities regulate the development, approval, classification, testing, manufacturing, labeling, marketing, and sale of medical devices. Likewise, our use and disclosure of certain categories of health information may be subject to federal and state laws, implemented and enforced by governmental authorities that protect health information privacy and security. For a description of these regulations, see Item 1, " Business, " under the subheading " Government Regulation. " The approval or clearance by governmental authorities, including the FDA in the U. S., is generally required before any medical devices may be marketed in the U. S. or other countries. We cannot predict whether, in the future, the U. S. or foreign governments may impose regulations that have a material adverse effect on our business, financial condition, results of operations, or cash flows. The process of obtaining FDA clearance and approvals to develop and market a medical device can be costly, time- consuming, and subject to the risk that such clearances or approvals will not be granted on a timely basis, if at all. The regulatory process may delay or prohibit the marketing of new products and impose substantial additional costs if the FDA lengthens review times for new devices. Further, the FDA has the ability to change the regulatory classification of a cleared or approved device from a higher to a lower regulatory classification, or to reclassify an HCT / P, either of which could materially adversely impact our ability to market or sell our devices. In addition, we must engage in extensive recordkeeping and reporting. For example, the Federal Medical Device Reporting regulation requires us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or that a malfunction occurred that would be likely to cause or contribute to a death or serious injury upon recurrence. We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA' s QSR and other regulations. Allegations may be made against us or against our suppliers, including donor recovery groups or tissue banks, claiming that the acquisition or processing of biomaterials products does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to investigate or take other action against us or our suppliers, or could cause negative publicity for us or our industry generally. If the FDA were to investigate us, because of an allegation or otherwise, and if the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines and civil penalties against us, our officers, our employees, or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third- party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. The FDA also has the authority to request repair, replacement, or refund of the cost of any medical device manufactured or distributed by us. The FDA may also recommend prosecution to the U. S. **DOJ** ~~Department of Justice~~. Any notice or communication from the FDA regarding a failure to comply with applicable requirements, or negative publicity or product liability claims resulting from any adverse regulatory action, could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations, or cash flows. We have little control over the ongoing compliance of our suppliers with applicable regulations. Their failure to comply may expose us to regulatory action and other liability, including fines and civil penalties, suspension of production, suspension or delay in new product approval or clearance, product seizure or recall, or withdrawal of product approval or clearance. Moreover, governmental authorities outside the U. S. have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non- U. S. governmental authorities in the future. U. S. or non- U. S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. The European Commission (" EC ") has harmonized national regulations for the control of medical devices through European Medical Device Directives with which manufacturers must comply. Under these new regulations, manufacturing plants must have received a full Quality Assurance Certification from a " Notified Body " in order to be able to sell products within the member states of the E. U. This Certification allows manufacturers to stamp the products of certified plants with a " CE " mark. Products covered by the EC regulations that do not bear the CE mark cannot be sold or distributed within the E. U. We have received certification for all currently existing manufacturing facilities. In addition, until a completed mutual recognition agreement exists between Switzerland and the E. U., Switzerland will be considered a Third Country. The company has, however, pursued registration of certain key products in Switzerland under their new laws. Similar activities have been pursued in the United Kingdom in relation to Brexit. The FDA, the U. S. Office of the Inspector General for the U. S. Department of Health and Human Services, the U. S. **DOJ,** ~~Department of Justice~~ and other regulatory agencies actively enforce regulations prohibiting the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside its cleared or approved indications is known as " off- label " use. Physicians may prescribe our products for off- label uses, as the FDA does not restrict or regulate a physician' s choice of treatment within the practice of medicine. However, if a regulatory agency determines that our promotional materials, training **,** or activities constitute improper promotion of an off- label use, the regulatory agency could request that we modify our promotional

materials, training , or activities, or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine , and / or criminal penalties. Although our policy is to refrain from statements and activities that could be considered off- label promotion of our products, any regulatory agency could disagree and conclude that we have engaged in off- label promotion and, potentially, caused the submission of false claims. Moreover, the off- label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. In addition, we may be subject to compliance actions, penalties, or injunctions if the FDA challenges one or more of our determinations that a product modification did not require new approval or clearance by the FDA. We have the market ~~–~~leading bone growth stimulation platform ~~with~~ **as** the only **company** ~~cervical spine indication granted by the FDA, and the only mobile device app accessory designed~~ to **provide both PEMF** ~~help patients adhere to their prescriptions~~ and **LIPUS bone healing solutions** ~~improve their clinical outcomes, STIM onTrack 2. 1. We also are investing in IDE studies to expand indications for use in areas such as rotator cuff tears~~ . Our bone growth therapy products currently are designated as Class III devices. Class III devices are subject to the FDA' s most rigorous pathway to approval for medical devices in the U. S. The FDA may change classification of a device only if the proposed new class has sufficient regulatory controls to provide reasonable assurances of safety and effectiveness. In September 2020, the FDA' s Orthopedic and Rehabilitation Devices Panel recommended that bone growth stimulator devices be reclassified from Class III to Class II devices with " special controls " to ensure patient safety and therapy efficacy. These proposed special controls include the condition that such devices be subject to rigorous clinical studies and post market surveillance for any new products. This would be in addition to other special controls and the Class II general requirement that any new products show " substantial equivalence " to already- cleared or approved devices. We believe that the panel' s recommendation correctly recognizes the importance of PMA- like clinical data for these devices, so that manufacturers will continue to be required to submit robust clinical data under the approval or clearance process to ensure the safety and efficacy of these devices for patients. We, along with other bone growth stimulation manufacturers, submitted comments in response to the FDA' s proposed rulemaking to underscore the panel' s recommendation of the need for robust clinical data prior to approval or clearance of bone growth stimulator products, together with post market surveillance requirements. In the long- term, the recommended reclassification could enhance the ability of competitors to enter the market if they are able to create technologies with comparable efficacy to our devices, which could result in our products facing additional competition, thereby negatively affecting our future sales of these products. We continue to be affected by U. S. healthcare reform initiatives. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (or collectively the " ACA "), has caused a number of substantial changes to occur in recent years in the way healthcare is financed by both governmental and private insurers. The ACA is far- reaching and is intended to expand access to health insurance coverage, improve quality, and reduce costs over time. Among other things, the ACA: • Established a Patient- Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and • Implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models. U. S. government agencies continue efforts to modify provisions of the ACA. For example, CMS began permitting states to impose work requirements on persons covered by Medicaid expansion plans, certain federal subsidies to insurers have ended, and certain short- term insurance plans not offering the full array of ACA benefits have been allowed to extend in duration. Some of these changes are being challenged in U. S. courts and so their long- term impact remains uncertain. This changing federal landscape has both positive and negative impacts on the U. S. healthcare industry, with much remaining uncertain as to how various provisions of federal law, and potential modification or repeal of these laws, will ultimately affect the industry. Persisting uncertainty with respect to the scope and effect of certain provisions of the ACA have made compliance costly. Any future changes to the ACA or other such legislation, depending on their nature, could affect rebates, prices, or the rate of price increases for health care products and services, or required reporting and disclosure, and could have an adverse effect on our ability to maintain or increase sales of any of our products and achieve profitability. We cannot predict the timing or impact of any future rulemaking or changes in the law. However, any changes that have the effect of reducing reimbursements for our products or reducing medical procedure volumes could have a material and adverse effect on our business, financial condition, and results of operations. We are subject to differing customs and import / export rules in several jurisdictions in which we operate. We import and export our products to and from a number of different countries around the world. Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to even more rigorous regulation by foreign governmental authorities. Numerous laws restrict, and in some cases prohibit, U. S. companies from directly or indirectly selling goods, technology , or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. Compliance with these regulations is costly. The import and export of our products involve subsidiaries and third parties operating in jurisdictions with different customs and import / export rules and regulations. Customs authorities in such jurisdictions may challenge our treatment of customs and import / export rules relating to product shipments under aspects of their respective customs laws and treaties. If we are unsuccessful in defending our treatment of customs and import / export classifications, we may be subject to additional customs duties, fines, or penalties that could adversely affect our profitability. In addition, changes in U. S. or foreign policies regarding international trade could also negatively impact our business. The enactment of or increases in tariffs, or other such charges, on specific products that we sell or with which our products compete, may have an adverse effect on our business or on our results of operations. The sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies. AdvaMed (U. S.), ~~EucoMed~~ **MedTech Europe** (Europe), MEDEC **and MedTech Canada** (Canada) , and MTAA (Australia), some of the principal trade associations for the medical device industry, have promulgated model codes of ethics that set forth standards by which its members should (and non- member companies may) abide in the promotion of their products in various

regions. We have implemented policies and procedures for compliance consistent with ~~those --~~ **the standards** promulgated by these associations, and we train our sales and marketing personnel on our policies regarding sales and marketing practices. Nevertheless, the sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies ~~, we~~ **. We** believe this trend will continue and that it could affect our ability to retain customers and other relationships important to our business. For example, prosecutorial scrutiny and governmental oversight, at both the state and federal levels, over some major device companies regarding the retention of healthcare professionals have limited how medical device companies may retain healthcare professionals as consultants. Various hospital organizations, medical societies **,** and trade associations are establishing their own practices that may require detailed disclosures of relationships between healthcare professionals and medical device companies **,** or ban or restrict certain marketing and sales practices, such as gifts and business meals. In addition, the ACA, as well as certain state laws, require detailed disclosure of ~~certain financial relationships, gifts~~ **expenses incurred on behalf of** and ~~other~~ remuneration made to certain healthcare professionals and teaching hospitals, the publicity surrounding which could have a negative impact on our relationships with our customers and ability to seek input on product design or involvement in research. As a result of laws, rules **,** and regulations **,** or our own or third- party policies that prohibit or restrict interactions, or the growing perception that any interaction between healthcare professionals and industry are tainted, we may be unable to engage with our healthcare professional customers in the same manner or to the same degree, or at all, as would otherwise be the case, which may adversely affect our ability to understand our customer' s needs and to incorporate into our development programs feedback that addresses these needs. If we are unable to develop and commercialize new products that address the needs of our physician customers and their patients, our products may not be broadly accepted in the marketplace, or at all, which would have a negative effect on our business, results of operations **,** and financial condition. Our research, development **,** and manufacturing processes involve the controlled use of certain hazardous materials. For example, our allograft bone tissue processing may generate waste materials that in the U. S. are classified as medical waste. In addition, we lease facilities at which hazardous materials could have been used. Because of the foregoing, we are subject to federal, state, foreign **,** and local laws and regulations governing the use, manufacture, storage, handling, treatment, remediation **,** and disposal of hazardous materials and certain waste products. Although we believe that our procedures for handling and disposing of hazardous materials comply with applicable laws as currently in effect, we cannot eliminate the risk of accidental contamination or injury from these materials. In addition, under some environmental laws and regulations, we could also be held responsible for all of the costs relating to any contamination at our past or present facilities and at third- party waste disposal sites, even if such contamination was not caused by us. If an accident occurs, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages **,** and fines ~~any~~ **. Any** related liability could exceed our resources. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations. We carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Risks Related to our Business and Industry The COVID- 19 pandemic ~~has materially adversely affected, and could continue to materially adversely affect, our operations, supply chain, manufacturing, product demand, product distribution, customers and other business activities. The novel coronavirus discovered in late 2019, and the disease it causes, known as COVID- 19, has led to significant disruptions in the healthcare market and the United States and international economies that may continue for a prolonged duration. The rapid spread of the coronavirus in 2020 and variants of the virus in 2021, the persistence of the resulting pandemic, the measures governments and private parties have implemented in order to stem the spread of this pandemic, and the general concern about the virus, have had, and could continue to have, a negative effect on the demand for many of our products compared to historical levels, and consequently upon our business. In particular, many of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times in 2020, 2021, and portions of 2022, in many of the markets where our products are marketed and sold, which negatively affected our business, cash flows, financial condition and results of operations. Deferrals of elective surgeries could result in delayed product launches if it takes longer than anticipated to collect feedback following an alpha launch. Further, facilities at which our products typically are used may not reopen or, even if they reopen, patients may elect to have procedures performed at facilities that are, or are perceived to be, lower- risk, such as ambulatory surgery centers, and our products may not be approved at such facilities, and we may be unable to have our products approved for use at such facilities on a timely basis, or at all. The future trajectory of the COVID- 19 pandemic remains uncertain, both in the U. S. and in other markets, particularly due to the uncertainty as to the nature of future variants, and whether vaccines will protect against severe illness with respect to such future variants. Given these various uncertainties, it is unclear the extent to which lingering slowdowns in elective procedures will continue to affect our business in 2023 and beyond. We expect that the effects of COVID- 19 on our business will depend on various factors including (i) the magnitude, length and virulence of additional case waves and future variants, (ii) the continued distribution, efficacy, refinement, and public acceptance of COVID- 19 vaccines, (iii) the comfort level of patients in visiting clinics and hospitals, and (iv) the extent to which further elective surgery slowdowns occur during periods when hospital capacity is stretched because of the need to treat COVID- 19 patients. In addition to its effect on elective surgeries, the pandemic could also negatively affect our ability, and the ability of our third- party suppliers, manufacturers, distributors, and customers, to retain key employees and ensure the continued service and availability of skilled personnel necessary to run our, and their, complex operations. To the extent our management or other personnel, or the management or other personnel of our third- party suppliers, manufacturers, distributors, and customers, are negatively affected by the pandemic and are not available to perform their job duties, we could experience delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial and corporate functions. Moreover, our relationships with our employees may be disrupted due to measures implemented in response~~

~~to the COVID- 19 pandemic. We have observed an overall tightening and increasingly competitive labor market due to labor shortages caused in part by the COVID- 19 pandemic and responsive measures, which has included increased wages offered by other employers and voluntary attrition of employees in the industry, including at third- party suppliers, manufacturers, distributors and customers. All of these factors, collectively, could materially adversely affect our business, financial condition and results of operations. The COVID- 19 pandemic~~ and related supply chain and raw material disruptions **previously had material adverse impacts to our** ~~, and the ongoing conflict between Russia and Ukraine, and the~~ global ~~response to it,~~ **operations and financial condition. Other such global events** could **similarly** have a ~~continuing~~ material impact on our global operations and the operations of our supply chain, which could adversely impact our business results and financial condition. We rely on a limited number of suppliers to manufacture or supply certain products or components. In the event of interruption within our supply chain, or global shortages of key supplies or components, we may not be able to increase capacity from other sources or develop alternative or secondary sources without incurring significant additional costs and / or substantial delays. For example, the COVID- 19 pandemic ~~has~~ **temporarily** led to a global shortage of semiconductor chips, which are used in certain of our products. This shortage ~~appears~~ **was** primarily ~~to have been~~ caused by manufacturers experiencing shutdowns or slowdowns during the pandemic, and it **took** ~~may take~~ several fiscal quarters ~~or longer~~ for normalized capacity to return. In addition, limitations in key raw material supplies could also cause semiconductor chip and other component shortages ~~to continue~~ **potentially in the future** . To the extent **such** ~~it continues, or more~~ shortages are experienced, particularly on a longer **-** term basis, this could adversely affect our ability to procure ~~such~~ **key** components and manufacture certain of our products or it could require us to redesign any affected products in order to incorporate more readily available components, which may require additional regulatory testing and approvals. Thus, our business could be adversely affected in a significant manner if one or more of our suppliers are impacted by any interruption at a particular location or in relation to a particular material or component ~~. The ongoing conflict between Russia and Ukraine has resulted in the implementation of sanctions by the United States and other governments against Russia and has caused significant volatility and disruptions to the global markets. It is not possible to predict the short- or long- term implications of this conflict, which could include but are not limited to further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, supply chain challenges and adverse effects on currency exchange rates and financial markets. In addition, the United States government reported that United States sanctions against Russia in response to the conflict could lead to an increased threat of cyberattacks against United States companies. These increased threats could pose risks to the security of our information technology systems and networks, as well as the confidentiality, availability and integrity of our data. A significant escalation or further expansion of the conflict' s current scope or related disruptions to the global markets could have a material adverse effect on our results of operations~~ . Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators, and third- party payors to curb these costs. As a result, there has been a trend toward healthcare cost containment through aggregating purchasing decisions and industry consolidation, along with the growth of managed care organizations, all of which has placed increased emphasis on the delivery of more cost- effective medical therapies. For example: • There has been consolidation among healthcare facilities and purchasers of medical devices, particularly in the U. S. One of the results of such consolidation is that GPOs, **IDNs,** ~~integrated delivery networks~~ and large single accounts use their market power to consolidate purchasing decisions, which intensifies competition to provide products and services to healthcare 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 its member hospitals and require us to discount, or limit our ability to increase, prices for certain of our products. In particular, certain of our ~~demineralized bone matrix (“~~ DBM ~~”)~~ products are priced at a premium to competitors' DBM products and a significant price reduction could result in a material adverse effect on our profitability. • Physicians increasingly have moved from independent, out- patient practice settings toward employment by hospitals and other larger healthcare organizations, which align physicians’ product choices with their employers’ price sensitivities and adds to pricing pressures. Hospitals have introduced and may continue to introduce new pricing structures into their contracts to contain healthcare 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 healthcare service and goods providers to reduce prices. • 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 healthcare industry. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and may continue to become more intense. This has resulted and may continue to result in greater pricing pressures and the exclusion of certain suppliers from important markets as GPOs, **IDNs** ~~independent delivery networks~~ , and large single accounts continue to use their market power to consolidate purchasing decisions and as larger manufacturers use their broad offerings to secure exclusive arrangements. If a GPO were to exclude us from their supplier list, our net sales could be adversely impacted. We expect that market demand, government regulation, third- party reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on the prices of our products. In addition, the largest 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. The industry in which we operate is highly competitive. New developments by others could make our products or technologies non- competitive or obsolete. The medical devices industry is highly competitive. We compete with a large number of companies, many of which have significantly greater financial, manufacturing, marketing, distribution, and technical resources than we do. Many of our competitors may be able to develop products and processes competitive with, or superior to, our own. Our competitors may also have: stronger intellectual property portfolios; broader spine surgery product

offerings and products supported by more extensive clinical data; more established distribution networks; entrenched relationships with physicians; significantly greater name recognition and more recognizable trademarks for products similar to the products we sell; more established relationships with healthcare providers and payors; greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancement; and greater experience in launching, marketing , and selling products than we do. Many of our competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are, or claim to be, superior to our products, or that are alternatives to our existing or planned products may also create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the spine market generally. Furthermore, we may not be able to successfully develop or introduce new products that are less costly or offer better performance than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. For more information regarding our competitors, see Item 1, " Business, " under the subheading " Competition. " In addition, the spine and orthopedic medical device industry in which we compete is undergoing, and is characterized by, rapid and significant technological change. We expect competition to intensify as technological advances are made. New technologies and products developed by other companies are regularly introduced into the market, which may render our products or technologies non- competitive or obsolete. Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third parties. Our ability to market our products successfully depends, in part, on the acceptance of the products by independent third parties (including hospitals, physicians, other healthcare providers, and third- party payors) as well as patients. Market acceptance for any of our products requires, among other things, that we timely secure regulatory clearance and / or approval; demonstrate the value of our products, both to our physician customers and payors, which may require that we collect clinical data and / or conduct clinical studies; effectively educate and train our physician customers and their staff on the proper use of our products; obtain and maintain coverage and adequate reimbursement for our products, both within and outside the U. S., including under Medicare and Medicaid and from private payors; attract and retain a network of independent sales agents and stocking distributors focused on neurophysicians and orthopedic spine physicians; develop and execute ~~an~~ effective marketing ~~strategy~~ **strategies** ; protect the proprietary positions of our products, including through patent protection; and consistently produce quality products in sufficient quantities to meet demand. Significant risks are associated with each of these activities and other activities required to achieve market acceptance of both our current and future products, including risks inherent in collaborations, or use of nascent manufacturing or imaging techniques, such as additive processing (more commonly known as 3D printing) or advanced optical technologies and machine version- based registration algorithms. Unanticipated side effects or unfavorable publicity concerning any of our products could have an adverse effect on our ability to maintain hospital approvals or achieve acceptance by prescribing physicians, managed care providers , and other retailers, customers, and patients. Clinical studies are expensive and subject to extensive regulation and their results may not support our product candidate claims or may result in the discovery of adverse effects. In developing new products or new indications for, or modifications to, existing products, we may conduct or sponsor pre- clinical testing, clinical studies , or other clinical research. We are conducting post- market clinical studies of some of our products to gather information about their performance or optimal use. The data collected from these clinical studies may ultimately be used to support additional market clearance or approval for these products or future products. If any of our new products require premarket clinical studies, these studies are expensive, the outcomes are inherently uncertain , and they are subject to extensive regulation and review by numerous governmental authorities , both in the U. S. and abroad, including by the FDA and, if federal funds are involved or if an investigator or site has signed a federal assurance, are subject to further regulation by the Office for Human Research Protections and the National Institutes of Health. For example, clinical studies must be conducted in compliance with FDA regulations, local regulations, and according to principles and standards collectively called " Good Clinical Practices. " Failure to comply with applicable regulations could result in regulatory and legal enforcement action, including fines, penalties, suspension of studies, and also could invalidate the data and make it unusable to support an FDA submission. Even if any of our future premarket clinical studies are completed as planned, we cannot be certain that their results will support our product candidates and / or proposed claims or that the FDA or foreign authorities and Notified Bodies will agree with our interpretation and conclusions regarding the data they generate. Success in pre- clinical studies and early clinical studies does not ensure that later clinical studies will succeed, and we cannot be sure that the results of later studies will replicate those of earlier or prior studies. The clinical study process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical studies will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patient subjects enrolled in our clinical studies of our marketed products will experience adverse side effects that are not currently part of the product candidate' s profile and, if so, these findings may result in lower market acceptance, which could have a material and adverse effect on our business, results of operations , and financial condition ~~. Further, the COVID- 19 pandemic could limit or restrict our ability or the ability of others on which we rely to initiate, conduct, or continue our clinical studies of some of our products. Delays and disruption in such studies could result in delays for expanded FDA and other regulatory clearance or approval of our products~~ . 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 contractually required or expected, we may not obtain regulatory clearance, approval , or a CE Certificate of Conformity for ~~or~~ **our products or be able to successfully** commercialize our products. We often must rely on third parties, such as contract research organizations, medical institutions, clinical investigators, and contract laboratories, to assist in conducting our clinical studies and other development activities. If these third parties do not successfully carry out their

contractual duties, comply with applicable regulatory obligations , or meet expected deadlines, or if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to failing to adhere to clinical protocols, to applicable regulatory requirements or otherwise, our pre- clinical development activities and clinical studies may be extended, delayed, suspended , or terminated. Under these circumstances, we may not be able to obtain regulatory clearance / approval or a CE Certificate of Conformity for ~~, or~~ **our products or be able to** successfully commercialize ~~,~~ our products on a timely basis, if at all, and our business, operating results , and prospects may be materially and adversely affected. Our allograft and cellular bone allografts could expose us to certain risks that could disrupt our business. ~~Our~~ **A portion of our** Biologics business markets allograft tissues that are derived from human cadaveric donors, and our ability to market the tissues depends on our supplier continuing to have access to donated human cadaveric tissue, as well as the maintenance of high standards by the supplier in its processing methodology. The supply of such donors is inherently unpredictable and can fluctuate over time. The allograft tissues are regulated under the FDA' s HCT / P regulatory paradigm and not as a medical device, biologic, or drug. There can be no assurance that the FDA will not at some future date re- classify the allograft tissues, and the reclassification of this product from a human tissue to a medical device could have adverse consequences for us or for the supplier of this product and make it more difficult or expensive for us to conduct this business by requiring premarket clearance or approval, as well as compliance with additional post- market regulatory requirements. In addition, procurement of certain human organs and tissue for transplantation is subject to the ~~National Organ Transplant Act (the "~~ NOTA ~~")~~ , which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control , and storage of human tissue and skin. If we were to be found to have violated NOTA' s prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E. U., as well as for other countries, the approval process in the E. U. for human- derived cell or tissue- based medical products could be extensive, lengthy, expensive , and unpredictable. Among others, some of our Biologics products are subject to E. U. member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage , and distribution of HCT / Ps. These E. U. member states' regulations include requirements for registration, listing, labeling, adverse- event reporting , and inspection and enforcement. Some E. U. member states have their own tissue banking regulations, including new requirements related to COVID- 19 and donor screening. Non- compliance with various regulations governing our products in any E. U. member state could result in the banning of our products in such member state or enforcement actions being brought against us, which could have a material and adverse effect on our business, results of operations , and financial condition. Unfavorable media reports or other negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our products. Unfavorable reports of improper or illegal tissue recovery practices, both in the U. S. and internationally, as well as incidents of improperly processed tissue leading to the transmission of disease, may affect the rate of future tissue donation and market acceptance of technologies incorporating human tissue. In addition, negative publicity could cause the families of potential donors to become reluctant to donate tissue to for- profit tissue processors. For example, the media has reported examples of alleged illegal harvesting of body parts from cadavers and resulting recalls conducted by certain companies selling human tissue- based products affected by the alleged illegal harvesting. These reports and others could have a negative effect on our tissue regeneration business. ~~Certain of our products contain materials derived from animal sources and may become subject to additional regulation. Certain of our products contain material derived from bovine tissue. Products that contain materials derived from animal sources, including food, pharmaceuticals and medical devices, are subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease from animals to humans via those materials. In past years, public scrutiny was particularly acute in Western Europe with respect to products derived from animal sources, largely due to concern that materials infected with the agent that causes BSE otherwise known as mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt- Jakob disease, an ultimately fatal disease with no known cure. Cases of BSE in cattle discovered in Canada and the U. S. increased awareness in North America. Products that contain materials derived from animals, including our products, could become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for the transmission of infectious or other agents. Significant new regulation, or a ban of our products, could have a material and adverse effect on our business or our ability to expand our business. Certain countries, such as Japan, China, Taiwan, and Argentina, have issued regulations that require our collagen products be processed from bovine tendon sourced from countries where no cases of BSE have occurred. The collagen raw material we use in our products is sourced from New Zealand. Our supplier has obtained approval from certain countries, including the U. S., the E. U., Japan, Taiwan, China, and Argentina, for the use of such collagen raw material in products sold in those countries. If we cannot continue to obtain collagen raw material from a qualified source of tendon from a country that has never had a case of BSE, we will not be permitted to sell our collagen products in certain countries, which could have a material and adverse effect on our business, results of operations and financial condition.~~ We may not be able to successfully introduce new products to the market and market opportunities that we expect to develop for our products may not be as large as we expect. To be and remain competitive, we need to continue to make improvements in our products, develop new products, introduce our products into new markets, and successfully respond to technological advances. Doing so is technologically challenging and involves significant risks and uncertainty. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex ~~and ,~~ uncertain, and involves risks. The success of any of our new product offerings or enhancement or modification to our existing products will depend on several factors, including our ability to: • properly identify and anticipate physician and patient needs; • develop new products ~~or~~ , enhancements , or modifications in a timely manner; • obtain regulatory clearance and / or approvals for new products or

product enhancements or modifications in a timely manner; • achieve timely alpha and / or full commercial launches of new products; • provide adequate training to potential users of new products and product enhancements or modifications; • receive adequate reimbursement approval of third- party payors such as Medicaid, Medicare , and private insurers; • gain broad market acceptance (including by physicians); and • ~~and~~ develop an effective marketing and distribution network. In addition, competitors could develop products that are more effective, ~~are~~ less expensive to manufacture, ~~are~~ priced more competitively , or that are ready for commercial introduction before our products. The introduction of new products by our competitors may lead us to reduce the prices of our products, result in ~~may lead to~~ reduced margins or loss of market share, and ~~may~~ / or render our products obsolete or noncompetitive. These risks make it inherently difficult to forecast and predict the future net sales of our products. If we cannot develop technically and commercially viable new products and enhancements or modifications to our existing products on a consistent basis and before our competitors, our prospects could be materially and adversely affected. In addition, if the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business. It is also important that we carefully manage our introduction of new products and enhancements or modifications to our existing products. If potential customers delay purchases until new or enhanced or modified products are available, it could negatively impact our sales. In addition, to the extent we have excess or obsolete inventory as we transition to new or enhanced or modified products, it would result in margin reducing write- offs for obsolete inventory, and our results of operations may suffer. There is no guarantee that the FDA will grant 510 (k) clearance or premarket approval, or that equivalent foreign regulatory authorities will grant the foreign equivalent, of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business. In general, unless an exemption applies, a medical device and modifications to the device or its indications must receive either premarket approval or premarket clearance from the FDA before it can be marketed in the U. S. While in the past we have received such clearances, we may not succeed in the future in receiving approvals and clearances in a timely manner, or at all. The process of obtaining approval or clearance from the FDA and comparable foreign regulatory agencies for new products, or for enhancements or modifications to existing products, could: • take significant time; • require the expenditure of substantial resources; • involve rigorous and expensive pre- clinical and clinical testing, as well as post- market surveillance; • involve modifications, repairs, or replacements of our products; and • result in limitations on the indicated uses of our products. Some of our new products will require FDA 510 (k) clearance or approval of a ~~premarket approval application, or~~ PMA ~~,~~ prior to being marketed. Any modification to a 510 (k)- cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, 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. Similarly, modifications to PMA- approved products may require submission and approval of a PMA supplement. The FDA requires every manufacturer to determine whether a new 510 (k) or PMA is needed in the first instance, and the FDA has issued guidance on assessing modifications to 510 (k)- cleared and PMA- approved devices to assist manufacturers with making these determinations. However, the FDA may review any such determination and the FDA may not agree with our determinations regarding whether new clearances or approvals are necessary. We have modified some of our 510 (k)- cleared products and have determined, based on our understanding of FDA guidance, that certain changes did not require new 510 (k) clearances. If the FDA disagrees with our determination and requires us to seek new 510 (k) clearances, or PMA approval, for modifications to our cleared products, we may have to stop marketing or distributing our products, we may need to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Significant delays in receiving clearance or approval, or failing to receive clearance or approval for our new products would have a material and adverse effect on our ability to expand our business. Outside the U. S., clearance or approval procedures can vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain clearance or approval in other countries might differ from that required to obtain FDA clearance or approval. The regulatory process in other countries may include all of the risks to which we are exposed in the U. S., as well as other risks. Favorable regulatory action in one country does not ensure favorable regulatory action in another, but a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others. Failure to obtain clearance or approval in other countries or any delay or setback in obtaining such clearance or approval have a material and adverse effect on our business, including that our products may not be cleared or approved for all indications requested, which could limit the uses of our products and have an adverse effect on product sales. In the European Economic Area (" EEA "), we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial change to our quality system or any significant change to our devices. The Notified Body will then assess the change and verify whether it affects the products' conformity with the Essential Requirements or the conditions for the use of the device. If the assessment is favorable, the Notified Body may issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity. If it is not, we may not be able to continue to market and sell the applicable product in the EEA, which could have a material and adverse effect on our business, results of operations and financial condition. We cannot be certain that we will receive required approval or clearance from the FDA and foreign regulatory agencies for new products, including modifications to existing products, on a timely basis, or at all. Failing to receive approval or clearance for new products on a timely basis would have a material and adverse effect on our financial condition and results of operations. Growing our business requires that we properly educate and train physicians regarding the distinctive characteristics, benefits, safety, clinical efficacy, and cost- effectiveness of our products. Acceptance of our products depends in part on our ability to (i) educate the medical community as to the distinctive characteristics, benefits, safety, clinical efficacy, and cost- effectiveness of our products compared to alternative products, procedures, and therapies, and (ii) train physicians in the proper use and implementation of our products. This is particularly true in instances of newly launched products or in the introduction of a product into a new market, such as our launch of the M6- C artificial cervical disc within the U. S. We support our sales force

and distributors through specialized training workshops in which physicians and sales specialists participate. We also produce marketing materials, including materials outlining surgical procedures, for our sales force and distributors in a variety of languages using printed, video, and multimedia formats. To provide additional advanced training for physicians, consistent with the AdvaMed Code and the MedTech Code, we organize regular multilingual teaching seminars in multiple locations. However, convincing physicians to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in our efforts to educate the medical community and properly train physicians. Physicians who do not use our products may be hesitant to do so for the following or other reasons: • lack of experience with our products, techniques, or technologies, or with the equipment necessary to use any of the foregoing; • existing relationships with those who sell competitive products; • the time required for physician and medical staff education and training on new products, techniques **,** and equipment and technologies; • lack or perceived lack of clinical evidence supporting patient benefit relative to competing products; • our products not being included on hospital formularies, in **IDNs,** ~~integrated delivery networks~~ or on **GPO** ~~group purchasing organization~~ preferred vendor lists; • less attractive coverage and / or reimbursement within healthcare payment systems for our products and procedures compared to other products and procedures; • other costs associated with introducing new products and the equipment necessary to use new products; and • perceived risk of liability that could be associated with the use of new products, techniques, or technologies. If physicians are not properly trained, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us. In addition, a failure to educate the medical community regarding our products may impair our ability to achieve market acceptance of our products. In addition, we believe recommendations and support of our products by influential physicians are essential for market acceptance and adoption. If we do not receive support from such physicians or long- term data does not show the benefits of using our products, physicians may not use our products. If we are not successful in convincing physicians of the merits of our products, we may not maintain or grow our sales or achieve or sustain profitability. Relatedly, although we believe our training methods for physicians are conducted in compliance with FDA and other applicable regulations developed both nationally and in third countries, if the FDA or other regulatory agency determines that our training constitutes promotion of an unapproved use or promotion of an intended purpose not covered by the CE mark affixed to our products or FDA approved labeling, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine **,** and **/ or** criminal penalty. Sales of, or the price at which we sell, our products may be adversely affected unless the safety and efficacy of our products, alone and relative to competitive products, is demonstrated in clinical studies. Generally, we have obtained 510 (k) clearance to manufacture, market **,** and sell the products we market in the U. S. and the right to affix the CE mark to the products we market in the EEA. To date, we have not been required to generate new clinical data to support our 510 (k) clearances, CE marks, or product registrations in other countries. However, the ~~EU~~ **E. U.** Medical Device Regulations, which replaced the prior medical device directives in May 2021, require submission of certain pre- and post- market data to maintain our CE marks. Additionally, we recently completed an analysis of which of our product systems will require submission of clinical data pursuant to MEDDEV 2. 7. 1 rev 4, which sets forth the **EC** ~~European Commission~~ ' s guidance on the clinical evaluation of medical devices. Accordingly, and in line with our vision to deliver clinical value, we have commenced clinical data collection activities for certain of our marketed products as more fully described elsewhere in this" Risk Factors" section. In part due to the increased emphasis on the delivery of more cost- effective treatments, purchasing decisions of our customers increasingly will be based on clinical data that demonstrates the value of our products or the effectiveness of our products relative to others. Conducting clinical studies is expensive and time- consuming and outcomes are uncertain. See " Clinical studies are expensive and subject to extensive regulation and their results may not support our product candidate claims or may result in the discovery of adverse effects, " above. We may elect not to, or may be unable to, fund the clinical studies necessary to generate the data required for all of our products to compete effectively, in part due to the breadth of our product portfolio. Currently, we do not expect to undertake such clinical studies for all of our products and only expect to do so where we anticipate the benefits will outweigh the costs on a risk- adjusted basis. However, even when we elect and are able to fund such clinical studies on one or more of our products, such studies may not succeed. Data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy, which could reduce demand for our products and negatively impact future sales. Neurophysicians and orthopedic spine physicians may be less likely to use our products if more robust, or any, clinical data supporting the safety and efficacy of competing products is available. If we are unable to or unwilling to generate clinical data supporting the safety and effectiveness of our products, our business, results of operations and financial condition could be materially and adversely affected. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. With the passage of the American Recovery and Reinvestment Act of 2009, funds have been appropriated for the U. S. Department of Health and Human Services' Healthcare Research and Quality to conduct comparative effectiveness research to determine the effectiveness of different drugs, medical devices, and procedures in treating certain conditions and diseases. Some of our products or procedures performed with our products could become the subject of such research. It is unknown what effect, if any, this research may have on our business. Further, future research or experience may indicate that treatment with our products does not improve patient outcomes or improves patient outcomes less than we initially expected. Such results would reduce demand for our products, affect sustainable reimbursement from third- party ~~payers~~ **payors** , significantly reduce our ability to achieve expected revenue, and could cause us to withdraw our products from the market and could prevent us from sustaining or increasing profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability, negative publicity, and damage to our reputation, and we could experience a dramatic reduction in sales of our products, all of which would have a material adverse effect on our business, financial condition, and results of operations. The spine medical device market has been particularly prone to potential product liability claims that are inherent in the testing, manufacture, and sale of medical devices and products

for spine surgery procedures. We may be adversely affected by any disruption in our information technology systems, which could adversely affect our cash flows, operating results, and financial condition. Our operations are dependent upon our information technology systems, which encompass all of our major business functions. We rely upon such information technology systems to manage and replenish inventory, fill and ship customer orders on a timely basis, coordinate our sales activities across all of our products and services, and coordinate our administrative activities. A substantial disruption in our information technology systems for any prolonged time period (arising from, for example, system capacity limits from unexpected increases in our volume of business, outages, or delays in service) could result in delays in receiving inventory and supplies or filling customer orders and adversely affect our customer service and relationships. Our systems might be damaged or interrupted by natural or man- made events, or by computer viruses, physical or electronic break- ins, and similar disruptions affecting the internet. There can be no assurance that such delays, problems, or costs will not have a material adverse effect on our cash flows, operating results, and financial condition. As our operations grow in both size and scope, we will continuously need to improve and upgrade our information technology systems and infrastructure while maintaining the reliability and integrity of our information technology systems and infrastructure. An expansion of our information technology systems and infrastructure may require us to commit substantial financial, operational, and technical resources before the volume of our business increases, with no assurance that the volume of business will increase. Any such upgrades to our information technology systems and information technology, or new technology, now and in the future, require that our management and resources be diverted from our core business to assist in integrating such upgrades or new technology. There can be no assurance that the time and resources our management will need to devote to these upgrades, service outages, or delays due to the installation of any new or upgraded technology (and customer issues therewith), or the impact on the reliability of our data from any new or upgraded technology, will not have a material adverse effect on our cash flows, operating results, and financial condition. A significant portion of our operations run on a single Enterprise Resource Planning (“ ERP ”) platform. To manage our international operations efficiently and effectively, we rely heavily on our ERP system, internal electronic information and communications systems, and on systems or support services from third parties. Any of these systems are subject to electrical or telecommunications outages, computer hacking, or other general system failure. It is also possible that future acquisitions will operate on different ERP systems and that we could face difficulties in integrating operational and accounting functions of new acquisitions. Difficulties in upgrading or expanding our ERP system or system- wide or local failures that affect our information processing could adversely affect our cash flows, operating results, and financial condition. We may be adversely affected by a failure or compromise from a cyber- attack, data breach or ransomware attack, which could have an adverse effect on our business. We rely on information technology systems to perform our business operations, including processing, transmitting, and storing electronic information, and interacting with customers, suppliers, healthcare payors, and other third parties. Like other medical device companies, the size and complexity of our information technology systems make them vulnerable to a cyber- attack, malicious intrusion, breakdown, destruction, loss of data privacy, ransomware attack, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect financial or personal information related to patients and customers, and changing customer patterns. For example, third parties may attempt to hack into our products to obtain data relating to patients, disrupt the performance of our products, or access our proprietary information. We could also be subject to a ransomware attack, which is a type of malicious software that infects a computer and restricts users' access to it until a ransom is paid to unlock it. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber- attacks, intrusions, or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations and could have a material adverse effect on our business, financial condition, and results of operations. In the U. S., Federal and State privacy and security laws require certain of our operations to protect the confidentiality of personal information including patient medical records and other health information. In Europe, the Data Protection Directive requires us to manage individually identifiable information in the E. U. and, the GDPR may impose fines of ~~up to~~ **the greater of 20 million Euros or** four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict the transfer or processing of that data. We are also subject to the California Consumer Privacy Act (the “ CCPA ”), which went into effect in January 2020. In November 2020, California passed the California Privacy Rights Act (the “ CPRA ”), which builds on the CCPA and expands consumer privacy rights to more closely align with the GDPR. The CPRA went into effect on January 1, 2023, and applies to information collected on or after January 1, 2022. The CCPA and CPRA, among other things, create new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. It remains unclear what, if any, additional modifications will be made to the CPRA by the California legislature or how it will be interpreted. We believe that we meet the expectations of applicable regulations and that the ongoing costs of compliance with such rules are not material to our business **,** but could become material due to new regulations. There is no guarantee that we will be able to comply with these regulations, or otherwise avoid the negative reputational and other effects that might ensue from a significant data breach or failure to comply with applicable data privacy regulations, each of which could have significant adverse effects on our business, financial condition, or results of operations. In recent years, companies around the world have seen a surge in wire transfer “ phishing ” attacks that attempt to trick employees into wiring money from company bank accounts to criminals’ bank accounts. In some cases, companies have lost millions of dollars to such relatively simple attacks, and these funds often are not recovered. While we take efforts to train employees to be cognizant of these types of attacks and take appropriate

precautions, the level of technological sophistication used by attackers has increased in recent years, and a successful attack against us could lead to the loss of significant funds. Although we possess insurance against the risk of cyber- attacks, there can be no assurance that the liability related to any such events will not exceed or insurance coverage limits or that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted. The physical effects of climate change or legal, regulatory **,** or market measures intended to address climate change could adversely affect our operations and operating results. Shifts in weather patterns caused by climate change are expected over time to increase the frequency, severity, or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures **,** or flooding, each of which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities **,** and other customers, reduced workforce availability, and increased costs of raw materials and components. While we do not expect climate change to materially affect the demand for our products, or the amount of persons with medical conditions we treat, climate change could also contribute to collateral effects such as increased transmission of viruses or airborne illnesses, which could contribute to unpredictable events, such as putting stress on ~~hospital~~ **hospitals** and other medical facilities and / or supply chains, and thus disrupting the elective surgery market in which we do business. In addition, increased public concern over climate change could result in new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material sourcing, manufacturing operations **,** and the distribution of our products, which could adversely affect our operations and operating results. If any of our manufacturing, development **,** or research facilities are damaged and / or **if** our manufacturing processes are interrupted, we could experience supply disruptions ~~,~~ **and / or** lost revenues and our business could be seriously harmed. Damage to our manufacturing, development **,** or research facilities **,** or disruption to our business operations for any reason, including due to natural disaster (such as earthquake, wildfires **,** and other fires or extreme weather), power loss, communications failure, unauthorized entry **,** or other events, such as a flu or other health epidemic (such as the result of the COVID- 19 pandemic), could cause us to discontinue development and / or manufacturing of some or all of our products for an undetermined period of time. The property damage and business interruption insurance coverage on these facilities that we maintain might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs. If our facilities were damaged, they could be difficult to replace and could require substantial lead time to repair or replace. In particular, we manufacture certain of our biologics products in one facility in Irvine, California **,** and any damage to that facility could adversely affect our ability to timely satisfy demand for those products. Out of an abundance of caution, in October 2020, we relocated part of our Biologics finished goods inventory from our Irvine facility to our Carlsbad office due to the threat of the Silverado Fire that was causing evacuations throughout Orange County, California. Disruptions to our business operations may result from damage to the facilities of, or disruption to the business operations of ~~,~~ our suppliers. For example, if we are unable to obtain disposables or other materials required to maintain " clean room " sterility in our Irvine facility, we may be unable to continue to manufacture products at that facility, which products accounts for a significant amount of our total revenue. Any significant disruption to our manufacturing operations and to our ability to meet market demand likely would have an adverse impact on our sales and revenues as key stakeholders, including our independent sales agents and stocking distributors and physician customers, transition to what they perceive as more reliable sources of products. We depend on third- party manufacturers for many of our products. We contract with third- party manufacturers to produce many of our products like many other companies in the medical device industry. If we or any such manufacturer fail to meet production and delivery schedules, it can have an adverse impact on our ability to sell such products. Further, whether we directly manufacture a product or utilize a third- party manufacturer, shortages and spoilage of materials, labor stoppages, product recalls, manufacturing defects, and other similar events can delay production and inhibit our ability to bring a new product to market in timely fashion. For example, the supply of the Trinity ELITE and Trinity Evolution allografts are derived from human cadaveric donors, and our ability to market the tissues depends on MTF continuing to have access to donated human cadaveric tissue and their continued maintenance of high standards in their processing methodology. We depend on a limited number of third- party suppliers for processing activities, components and raw materials and losing any of these suppliers, or their inability to provide us with an adequate supply of materials that meet our quality and other requirements, could harm our business. Outside suppliers, some of whom are sole- source suppliers, provide us with products ~~and ,~~ raw materials **,** and components used in manufacturing our ~~biologics and spinal implant~~ products. We strive to maintain sufficient inventory of products, raw materials **,** and components so that our production will not be significantly disrupted if a particular product, raw material **,** or component is not available to us for a period of time, including as a result of a supplier' s loss of its ISO or other certification or as a result of any of the disruptions described below under the risk factor titled " If any of our manufacturing, development **,** or research facilities are damaged and / or **if** our manufacturing processes are interrupted, we could experience supply disruptions ~~,~~ **and / or** lost revenues and our business could be seriously harmed. " For example, a certain number of our products require titanium, which is sourced from third party suppliers. While the titanium required for such products is not directly sourced from Russia, the current geopolitical events involving Russia and Ukraine is negatively impacting the wider titanium supply chain and such geopolitical events and factors relating thereto or resulting therefrom, including the imposition of sanctions, may negatively impact the ability of our local supply sources to timely supply titanium to us. In addition, some of our suppliers may choose to discontinue making their products available in the ~~EU~~ **E. U.** rather than follow MDR, which would require us to identify alternate supply sources for those products. Any such disruption in our production could harm our reputation, business, financial condition **,** and results of operations. Although we believe there are alternative supply sources, replacing our suppliers may be impractical or difficult in many instances. For example, we could

have difficulty obtaining similar services or products from other suppliers that are acceptable to the FDA or other foreign regulatory authorities and who are able to provide the appropriate supply volumes at an acceptable cost. In addition, if we are required to transition to new suppliers for certain services or components of our products, the use of services, components, or materials furnished by these alternative suppliers could require us to alter our operations, and if we are required to change the manufacturer of a critical component of our products, we will have to verify that the new manufacturer maintains facilities, procedures , and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time- consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products, or could require that we modify the design of those systems. If we are unable to obtain sufficient quantities of ~~spinal implant~~ products, raw materials , or components that meet our quality and other requirements on a timely basis for any reason, we may not produce sufficient quantities of our products to meet market demand until a new or alternative supply source is identified and qualified and, as a result, we could lose customers, our reputation could be harmed and our business could suffer. Furthermore, an uncorrected defect or supplier' s variation in a component or raw material that is incompatible with our manufacturing, or unknown to us, could harm our ability to manufacture products. Further, under the **Food and Drug Administration Safety and Innovation Act (" FDASIA ")** , which includes the Medical Device User Fee Amendments of 2012, as well as other medical device provisions, all U. S. and foreign manufacturers must have a FDA Establishment Registration and complete Medical Device listings for sales in the U. S. While we believe that our facilities materially comply with these requirements, we also source products from foreign contract manufacturers. It is possible that some of our foreign contract manufacturers will not comply with applicable requirements and choose not to register with the FDA. In such an event, we will need to determine if there are alternative foreign contract manufacturers who comply with the applicable requirements. If such a foreign contract manufacturer is a sole supplier of one of our products, there is a risk that we may not be able to source another supplier. Furthermore, we rely on a small number of tissue banks accredited by the **AATB** ~~American Association of Tissue Banks~~ for the supply of human tissue, a crucial component of our biologics products that serve as bone graft substitutes. Any failure to obtain tissue from these sources or to have the tissue processed by these sources for us in a timely manner will interfere with our ability to meet demand for our biologics products effectively. The processing of human tissue into biologics products is labor intensive and maintaining a steady supply stream is challenging. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our biologics products are at times in particularly short supply. If governments require additional donor testing due to COVID- 19, this could also strain the supply of tissue. We cannot be certain that our supply of human tissue from our suppliers will be available at current levels or will meet our needs or that we will be able to successfully negotiate commercially reasonable terms with other accredited tissue banks. If we are unable to maintain and expand our network of independent sales representatives and distributors, we may not maintain or grow our revenue. We sell our products in many countries through independent sales representatives and distributors. Frequently, our independent sales representatives and our distributors have the exclusive right to sell our products in their respective territories. If any of our independent sales representatives or distributors fail to adequately promote, market , and sell our products, our sales could significantly decrease. The terms of our agreements with our independent sales representatives and distributors vary in length, generally from one to ten years. Under the terms of our standard distribution agreements, each party has the right to terminate in the event of a material breach by the other party and we generally have the right to terminate if the distributor does not meet agreed sales targets or fails to make payments on time. Any termination of our existing relationships with independent sales representatives or distributors could have an adverse effect on our business unless and until commercially acceptable alternative distribution arrangements are put in place. In addition, we operate in areas of the world that have been or may be disproportionately affected by recessions or disasters and we bear risk that existing or future accounts receivable may be uncollected if these distributors or hospitals experience disruptions to their business that cause them to discontinue paying ongoing accounts payable or become insolvent. Further, we face significant challenges and risks in managing our geographically dispersed distribution network and retaining the independent sales representatives and distributors who make up that network, and as we launch new products and increase our marketing efforts with respect to existing products, we plan to expand the reach of our marketing and sales efforts and may need to hire new independent sales representatives and distributors. Independent sales representatives and distributors require significant technical expertise in various areas such as spinal care practices, spine injuries and disease, and spinal health and they require training and time to achieve full productivity. We may not attract or retain qualified independent sales representatives and distributors or enter into agreements with them on favorable or commercially reasonable terms, if at all. This could be due to a number of factors, including, but not limited to, perceived deficiencies, or gaps, in our existing product portfolio, intense competition for services of independent sales representatives and distributors, or because of the disruption associated with restrictive covenants to which representatives or distributors may be subject and potential litigation and expense associated therewith. We may also experience unforeseen disengagement from independent sales representatives and distributors who have worked with us for many years. Even if we enter into agreements with additional qualified independent sales representatives or distributors, it often takes 6 to 12 months for new sales representatives or distributors to reach full operational effectiveness and they may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products, or ultimately succeed in selling our products. Our success will depend largely on our ability to continue to hire, train, retain , and motivate qualified independent sales representatives and distributors. If we cannot expand our sales and marketing capabilities domestically and internationally, if we fail to train new independent sales representatives and distributors adequately, or if we experience high turnover in our sales network, we may not commercialize our products adequately, or at all, which would adversely affect our business, results of operations and financial condition. Moreover, because our independent sales representatives and distributors are not our employees, we have limited control over their activities and, generally, we do not enter into exclusive relationships with them. If

one or more of them were to be retained by a competitor, whether or an exclusive or non- exclusive basis, they may divert business from us to our competitor, which could materially and adversely affect our sales. ~~We depend on our senior management team. Our success depends upon the skill, experience, and performance of members of our senior management team, who have been critical to the management of our operations and the implementation of our business strategy. We do not have key man insurance on our senior management team, and the loss of one or more key executive officers could have a material adverse effect on our operations. Further, any turnover in our senior management team could adversely affect our operating results and cash flows.~~ In order to compete, we must attract, retain, and motivate **executives and** key employees, and our failure to do so could have an adverse effect on our results of operations. In order to compete, we must attract, retain, and motivate executives and other key employees, including those in managerial, technical, sales, marketing, research, development, finance, information and technology, and other support positions representing diverse backgrounds, experiences, and skill sets. Hiring and retaining qualified executives, engineers, technical staff, and sales representatives is critical to our business, and competition for experienced employees in the medical device industry can be intense. Maintaining our brand and reputation, as well as a diverse and inclusive work environment that enables all our employees to thrive, are important to our ability to recruit and retain employees. If we are less successful in our recruiting efforts, or if we cannot retain highly skilled workers and key leaders, our ability to develop and deliver successful products and services may be adversely affected. Moreover, replacing key employees may be a difficult, costly, and protracted process, and we may not have other personnel with the capacity to assume all of the responsibilities of a departing employee. Competition for qualified personnel, particularly for key positions, is intense among companies in our industry, and many of the organizations against which we compete for qualified personnel have greater financial and other resources and different risk profiles than **us** ~~our company~~, which may make them more attractive employers. All of our employees, including our management personnel, may terminate their employment with us at any time without notice. If we cannot attract and retain highly qualified personnel, as needed, we may not achieve our financial and other goals. To attract, retain, and motivate qualified executives and key employees, we utilize stock- based incentive awards, such as employee stock options ~~,~~ and restricted stock units. Certain awards vest based upon the passage of time while others vest upon the achievement of certain performance- based **and /** or market- based conditions. If the value of such stock awards does not appreciate, as measured by the performance of the price of our common stock, and ceases to be viewed as a valuable benefit, our ability to attract, retain, and motivate our employees could be adversely impacted, which could negatively affect our results of operations and / or require us to increase the amount we expend on cash and other forms of compensation. In addition, future internal growth could impose significant added responsibilities on our management, and we will need to identify, recruit, maintain, motivate, and integrate additional employees to manage growth effectively. If we do not effectively manage such growth, our expenses may increase more than expected, we may not achieve our goals, and our ability to generate and / or grow revenue could be diminished. Because we sell our products in many different countries, our business is subject to risks associated with conducting business internationally. We anticipate that net sales from international operations will continue to represent a substantial portion of our total net sales. In addition, certain of our manufacturing facilities and suppliers are located outside the U. S. Accordingly, our future results could be harmed by a variety of factors, including: • changes in a specific country' s or region' s political, social, or economic conditions; • difficulties in staffing and managing widespread operations; • having to comply with export control laws, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce; • complex data privacy requirements, including, but not limited to, the GDPR; • differing regulatory requirements for obtaining clearances or approvals to market our products, and unexpected changes in regulatory requirements; • changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the U. S.; • tariffs, trade barriers ~~and~~ **,** export regulations **, and other regulatory and contractual limitations** that **may** adversely impact ~~, and other regulatory and contractual limitations on,~~ our ability to sell our products in certain foreign markets, the scope and consequences of which are subject to changing agendas of political, business **,** and environmental groups; • consequences from changes in tax or customs laws; • fluctuations in foreign currency exchange rates; • limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures; • differing multiple ~~payer~~ **payor** reimbursement regimes, government ~~payers~~ **payors ,** or patient self- pay systems; • differing labor laws and standards; • an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; • availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us; and • having to comply with various U. S. and international laws, including the FCPA and anti- money laundering laws, and violation by our independent sales representatives or distributors of such laws. Risks Related to our Intellectual Property We depend on our ability to protect our intellectual property and proprietary rights, but we may not be able to maintain the confidentiality of these assets or assure their protection. Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products that are similar to, or that compete directly with, our products. Numerous patents covering our technologies have been issued to us and we have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the U. S. Some patent applications in the U. S. are maintained in secrecy until the patent is issued. Because the publication of discoveries tends to follow their actual discovery by several months, we may not be the first to invent or file patent applications on any of our discoveries. Further, there is a substantial backlog of patent applications at the U. S. Patent and Trademark Office, and the approval or rejection of patent applications may take several years. Patents may not be issued with respect to any of our patent applications and existing or future patents issued to or licensed by us and may not provide adequate protection or competitive advantages for our products. Patents that are issued may be challenged, invalidated, or circumvented by our

competitors. Furthermore, our patent rights may not prevent our competitors from developing, using, or commercializing products that are similar or functionally equivalent to our products. Moreover, if patents are not issued with respect to our products arising from research, we may not be able to maintain the confidentiality of information relating to these products. In addition, if a patent relating to any of our products lapses or is invalidated, we may experience greater competition arising from new market entrants. We also rely on trade secrets, unpatented proprietary expertise, and continuing technological innovation that we protect, in part, by entering into confidentiality agreements with assignors, licensees, suppliers, employees, and consultants. These agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of confidentiality agreements. Moreover, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using 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, adequately protect 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. We may face claims by third parties that our agreements with employees, consultants , or advisors obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are unsuccessful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the U. S., if at all. Since certain of our issued patents and pending patent applications are for the U. S. only, we lack a corresponding scope of patent protection in other countries. Thus, we may not be able to stop a competitor from marketing products in other countries that are similar to some of our products. If we are unable to obtain, protect , and enforce patents on our technology and to protect our trade secrets, such inability could have a material and adverse effect on our business, results of operations, and financial condition. Third parties may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products. Our success will depend in part on our ability, both in the U. S. and in foreign countries, to operate without infringing upon the patents and proprietary rights of others, and to obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur. There has been substantial litigation in the medical device industry with respect to the manufacture, use, and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to defend against allegations relating to the infringement of patent or proprietary rights of third parties. Any such litigation could, among other things: • Require us to incur substantial expense, even if we are successful in the litigation; • Require us to divert significant time and effort of our technical and management personnel; • Result in the loss of our rights to develop or make certain products; and • Require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties or to satisfy judgments or to settle actual or threatened litigation. Although patent and intellectual property disputes within the medical devices industry have often been settled through assignments, licensing, or similar arrangements, costs associated with these arrangements may be substantial and could include the long- term payment of royalties. Accordingly, an adverse determination in a judicial or administrative proceeding, or a failure to obtain necessary assignments or licenses, could result in us having to pay substantial damages (which may be increased up to three times of awarded damages) and / or substantial royalties, and could prevent us from manufacturing or selling some products or increase our costs to market these products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations , and financial condition. In addition, we generally indemnify our customers and sales representatives with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or sales representatives. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or sales representatives, regardless of the merits of these claims. If any of these claims succeed, we may be forced to indemnify, or pay damages on behalf of, our customers or sales representatives or may have 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 seek to protect or enforce our intellectual property rights through litigation or other proceedings, it could require us to spend significant time and money, the results of which are uncertain. To protect or enforce our intellectual property rights, we may have to initiate or defend litigation against or by third parties, such as infringement suits, opposition proceedings, or seeking a court declaration that we do not infringe the proprietary rights of others or that their rights are invalid or unenforceable. We may not have sufficient resources to enforce our intellectual property rights or to defend our intellectual property rights against a challenge. Even if we prevail, the cost of litigation, including the diversion of management and other resources, could affect our profitability and could place a significant strain on our financial resources. Our ability to enforce our intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement

in a competitor' s or potential competitor' s product. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. In addition, the patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity **,** and enforceability of any patent claims we have or may obtain cannot be predicted with certainty. We may be subject to claims that we, our employees, or our independent sales agents or stocking distributors have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. Many of our employees were employed at other medical device companies, including our competitors or potential competitors, **and** in some cases **, were employed at such medical device companies** immediately prior to joining us. In addition, many of our independent sales representatives and distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees **,** or our independent sales representatives or distributors intentionally, inadvertently **,** or otherwise used or disclosed trade secrets or other proprietary information of former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee, or encouraged / assisted an independent sales agent, to breach the terms of his or her non- competition or non- solicitation agreement. Litigation may be necessary to defend against these claims. Litigation is expensive and time- consuming, and could divert management attention and resources away from our business. Even if we prevail, the cost of litigation could affect our profitability. If we do not prevail, in addition to any damages we might have to pay, we may lose valuable intellectual property rights or employees, independent sales representatives **,** or distributors. There can be no assurance that this type of litigation or the threat thereof will not adversely affect our ability to engage and retain key employees, sales representatives **,** or distributors. Risks Related to Litigation and Product Liability Matters We may be subject to product and other liability claims that may not be covered by insurance and could require us to pay substantial sums. We are subject to an inherent risk of, and adverse publicity associated with, product liability and other liability claims, whether or not such claims are valid. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, if neurosurgeons and orthopedic spine surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects, or inadequate disclosure of product- related risks or product- related information resulted in an unsafe condition or injury to patients. In addition, the development of allograft implants and technologies for human tissue repair and treatment may entail particular risk of transmitting diseases to human recipients, and any such transmission could result in the assertion of product liability claims against us. Product liability claims are expensive to defend, divert our management' s attention and, if we are not successful in defending the claim, can result in substantial monetary awards against us or costly settlements. Further, successful product liability claims made against one or more of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Any product liability claim brought against us, with or without merit and regardless of the outcome or whether it is fully pursued, may result in: decreased demand for our products ~~;~~**,** injury to our reputation ~~;~~**,** significant litigation costs ~~;~~**,** product recalls ~~;~~**,** loss of revenue ~~;~~**,** the inability to commercialize new products or product candidates ~~;~~**,** and adverse publicity regarding our products. Any of these may have a material and adverse effect on our reputation with existing and potential customers and on our business, financial condition, and results of operations. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers. We maintain product liability insurance coverage in amounts and scope that we believe are reasonable and adequate. There can be no assurance, however, that product liability or other claims will not exceed our insurance coverage limits or that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. A successful product liability claim that exceeds our insurance coverage limits could require us to pay substantial sums and could have a material adverse effect on our financial condition. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers. Our insurance policies are expensive and protect us only from some risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk to which our business is or may be exposed. Some of the policies we maintain include product liability insurance, directors' and officers' liability insurance, property **insurance, cybersecurity insurance, general liability** insurance, and workers' compensation insurance. We do not know, however, if we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted. Even if we have insurance, a claim could exceed the amount of our insurance coverage or it may be excluded from coverage under the terms of the policy. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. Risks Related to Potential Acquisitions, Investments, and Divestitures Our efforts to identify, pursue, and implement new business opportunities (including acquisitions) may be unsuccessful and may have an adverse effect on our business. Our growth depends, in large part, on our ability to identify, pursue, and implement new business opportunities that expand our product offerings, capabilities, and geographic presence, and we compete with other medical device companies for these opportunities. Our efforts to identify such opportunities focus primarily on potential acquisitions of new businesses, products or technologies, licensing arrangements, commercialization arrangements, and other transactions with third parties. We may not be able to identify business opportunities that meet our strategic criteria or that are acceptable to us or our stockholders. Even if we are able to identify acceptable business opportunities, we may not be able to pursue or implement such business opportunities (or, in the case of acquisitions or other transactions, complete such acquisitions or other transactions) in a timely manner or on a cost- effective basis (or at all), and we may not realize the expected benefits of such business opportunities. If we are not able to identify, pursue, and implement new business opportunities, it will adversely affect our ability to grow our business. In addition,

pursuing and implementing new business opportunities (particularly acquisitions) may involve significant costs and entail risks, uncertainties, and disruptions to our business, especially where we have limited experience as a company developing or marketing a particular product or technology or operating in a particular geographic region. We may be unable to integrate a new business, product, or technology effectively, or we may incur significant charges related to an acquisition or other business opportunity (for example, amortization of acquired assets or asset impairment charges), which may adversely affect our business, financial condition, and results of operations. Newly acquired technology or products may require additional development efforts prior to commercial sale, including clinical testing and approval by the FDA and applicable foreign regulatory authorities; such additional development efforts may involve significant expense and ultimately be unsuccessful. Any cross- border acquisitions or transactions may involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks, and the particular economic, political, and regulatory risks associated with specific countries. To the extent we issue additional equity in connection with acquisitions, this may dilute our existing stockholders. Furthermore, as a result of acquisitions of other healthcare businesses, we may be subject to the risk of unanticipated business uncertainties, regulatory and other compliance matters **,** or legal liabilities relating to those acquired businesses for which the sellers of the acquired businesses may not indemnify us, for which we may not be able to obtain insurance (or adequate insurance) or for which the indemnification may not be sufficient to cover the ultimate liabilities. We have provided over $ 10. 0 million in investments and loans to a privately- held company in Switzerland and may not be able to recoup our investment. In October 2020, we entered into agreements with Neo Medical SA, a privately- held Swiss-based medical technology company developing a new generation of products for spinal surgery (" Neo Medical "). Our collaboration with Neo Medical focuses on co- developing with them a cervical platform and deploying single- use, sterile-packed procedure solutions designed to increase operating room efficiencies, reduce procedural times and costs, improve patient outcomes through novel device designs and techniques, and reduce infection rates. These instruments are designed for surgical settings including acute care hospitals, outpatient hospitals, and also **ASCs** ~~ambulatory surgery centers~~. Under our agreements with Neo Medical, we will also exclusively distribute Neo Medical' s thoracolumbar procedure solutions to certain U. S. accounts. In connection with these arrangements, we purchased $ 5. 0 million of Neo Medical' s preferred stock ~~,~~ and loaned CHF 4. 6 million ($ 5. 0 million as of the issuance date) to Neo Medical pursuant to a convertible loan agreement. The loan accrues interest at an annual rate of 8 % and is convertible by either party into additional shares of Neo Medical' s preferred stock. If not otherwise converted to preferred stock in the interim, the loan and all accrued interest become due and payable in October 2024. In October 2021, the Company entered into an additional Convertible Loan Agreement (the " Additional Convertible Loan "), pursuant to which the Company loaned Neo Medical an additional CHF 0. 6 million ($ 0. 7 million as of the issuance date). In January 2022, the Company elected to convert the Additional Convertible Loan into shares of Neo Medical' s preferred stock. Neo Medical is using the proceeds of our preferred stock purchase and loans to fund its ongoing operations. However, no assurance can be made that Neo Medical' s business ultimately will be successful. As such, we could ultimately be unable to recoup any value for the preferred stock that we purchased and / or unable to recoup the amount of our loan. We may incur significant costs or retain liabilities associated with disposition activity. We may from time to time sell, license, assign, or otherwise dispose of or divest assets, the stock of subsidiaries, or individual products, product lines, or technologies, which we determine are no longer desirable for us to own, some of which may be material. Any such activity could result in us incurring costs and expenses from these efforts, some of which could be significant. This may also result in us retaining liabilities related to the assets or properties disposed of even though, for instance, the income- generating assets have been disposed. These costs and expenses may be incurred at any time and may have a material impact on our results of operations. Risks Related to Our Financial Results and Need for Financing Our quarterly operating results may fluctuate. Our quarterly operating results have fluctuated significantly in the past. Our future quarterly operating results may fluctuate significantly and we may experience losses depending on a number of factors, many of which are outside our control. Such factors include: • economic conditions worldwide, ~~including arising from or relating to the effects of the COVID- 19 pandemic,~~ which could affect the ability of hospitals and other customers to purchase our products and could result in a reduction in elective and non- reimbursed operative procedures; • increased competition; • market acceptance of our existing products, as well as products in development, and the demand for, and pricing of, our products and the products of our competitors; • costs, benefits **,** and timing of new product introductions; • the timing of or failure to obtain regulatory clearances or approvals for new products; • lost sales and other expenses resulting from stoppages in our **production** or **from** third parties ~~' production~~ **supplying our business**, including as a result of product recalls or field corrective actions; • the availability and cost of components and materials, including raw materials such as human tissue; • accurate predictions of product demand and production capabilities sufficient to meet that demand; • our ability to realize expected yield improvements and scrap reduction initiatives that we have undertaken ~~at our Irvine facility~~; • higher than anticipated independent sales representatives and distributors commissions; • our ability to purchase or manufacture and ship our products efficiently and in sufficient quantities to meet sales demands; • the timing of our research and development expenditures; • expenditures for major initiatives; • the timing and level of reimbursement, changes in reimbursement or denials in coverage for our products by third- party payors, such as Medicare, Medicaid, private and public health insurers **,** and foreign governmental health systems; • the ability of our independent sales representatives and distributors to achieve expected sales targets and for new agents and stocking distributors to become familiar with our products in a timely manner **; • the timing of and our ability to successfully onboard and / or hire new sales agents and distributors; • the loss of certain customers, sales agents, or distributors, or the removal of our contractual ability to sell to certain customers, hospitals, or healthcare providers**; • peer- reviewed publications discussing the clinical effectiveness of our products; • inspections of our manufacturing facilities for compliance with the FDA ~~'~~ **'** s Quality System Regulations (Good Manufacturing Practices), which could result in Form 483 observations, warning letters, injunctions **,** or other adverse findings from the FDA or equivalent foreign regulatory bodies, and corrective actions, procedural changes **,** and

other actions, including product recalls, that we determine are necessary or appropriate to address the results of those inspections, any of which may affect production and our ability to supply our customers with our products; • the costs to comply with new regulations from the FDA or equivalent foreign regulatory bodies, such as the requirements to establish a unique device identification system to adequately identify medical devices through their distribution and use; • the increased regulatory scrutiny of certain of our products, including products we manufacture for others, which could result in ~~their~~ **them** being removed from the market; • fluctuations in foreign currency exchange rates; and • the impact of acquisitions, including the impact of goodwill and intangible asset impairment charges, if future operating results of the acquired businesses are significantly less than the results anticipated at the time of the acquisitions. In addition, we may experience meaningful variability in our sales and gross profit among quarters, as well as within each quarter, as a result of several factors, including but not limited to (and in addition to those listed above): • the number of products sold in the quarter; • the unpredictability of sales of full sets of spinal implants and instruments to our international stocking distributors; and • the number of selling days in the quarter. Our goodwill, intangible assets **,** and fixed assets are subject to potential impairment; we have recorded significant goodwill impairment charges **in the past** and may be required to record additional charges to future earnings if our remaining goodwill or intangible assets become impaired. A significant portion of our assets consists of goodwill, intangible assets **,** and fixed assets. The carrying value of these assets may be reduced if we determine that those assets are impaired, including intangible assets from recent acquisitions. Most of our intangible and fixed assets have finite useful lives and are amortized or depreciated over their useful lives on a straight- line basis. The underlying assumptions regarding the estimated useful lives of these intangible assets are analyzed on at least an annual basis and more often if an event or circumstance occurs making it likely that the carrying value of the assets may not be recoverable. Any such changes are adjusted through accelerated amortization, if necessary. Whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable, we test intangible assets for impairment based on estimates of future cash flows. Factors that may be considered a change in circumstances indicating that the carrying value of our intangible assets and / or goodwill may not be recoverable include a decline in stock price and market capitalization, slower growth rates in our industry, the introduction of newer technology or competing products that may cannibalize future sales, or other materially adverse events that have implications on the profitability of our business. When testing for impairment of finite- lived intangible assets held for use, we group assets at the lowest level for which cash flows are separately identifiable. If an intangible asset is considered to be impaired, the amount of the impairment will equal the excess of the carrying value over the fair value of the asset. Goodwill is required to be tested for impairment at least annually. We review our two reporting units for potential goodwill impairment in the fourth fiscal quarter of each year as part of our annual goodwill impairment testing, and more often if an event or circumstance occurs making it likely that impairment exists. During the fourth quarter of 2021, we recorded a full impairment of the Global Orthopedics goodwill. This resulted in an impairment charge of $ 11. 8 million, which is reflected within acquisition- related amortization and remeasurement on the Consolidated Statement of Operations. If actual results differ from the assumptions and estimates used in the goodwill and intangible asset calculations, we could incur future impairment or amortization charges, which could negatively impact our financial condition and results of operations. We face risks related to foreign currency exchange rates. Because some of our revenue, operating expenses, assets, and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses or recognize net sales in currencies other than the U. S. Dollar, any change in the values of those foreign currencies relative to the U. S. Dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our current assets denominated in foreign currency are greater or less than our current liabilities denominated in foreign currencies, we have potential foreign exchange exposure. The fluctuations of foreign exchange rates during ~~2022~~ **2023** had ~~an~~ **a** ~~unfavorable~~ -- **favorable** impact of $ ~~10~~ **2** . ~~5~~ **3** million on net sales outside of the U. S. Although we seek to manage our foreign currency exposure by matching non- dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we may enter into currency hedges from time to time. In addition, for those foreign customers who purchase our products in U. S. Dollars, currency exchange rate fluctuations between the U. S. Dollar and the currencies in which those customers do business may have a negative effect on the demand for our products in foreign countries where the U. S. Dollar has increased in value compared to the local currency. Converting our earnings from international operations to U. S. Dollars for use in the U. S. can also raise challenges, including problems moving funds out of the countries in which the funds were earned and difficulties in collecting accounts receivable in foreign countries where the usual accounts receivable payment cycle is longer. Our global operations may expose us to tax risks. We are subject to taxes in the U. S. and numerous foreign jurisdictions. Significant judgment and interpretation of tax laws are required to estimate our tax liabilities. Tax laws and rates in various jurisdictions may be subject to significant change as a result of political and economic conditions. Our effective income tax rate could be adversely affected by changes in those tax laws, changes in the mix of earnings among tax jurisdictions, changes in the valuation of our deferred tax assets and liabilities, vesting of equity awards at a price below the original valuation, historical entity classification elections, and the resolution of matters arising from tax audits. Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to amortize such expenditures over five years, or 15 years for such expenditures incurred outside of the U. S. This requirement may have a significant impact on our cash tax liability and our effective tax rate as we perform research and development in the U. S., Italy, and Canada. Certain of our subsidiaries sell products directly to other Orthofix subsidiaries or provide marketing and support services to other Orthofix subsidiaries. These intercompany sales and support services involve subsidiaries operating in jurisdictions with differing tax rates and we must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Tax authorities in these jurisdictions may challenge our treatment of such intercompany transactions. If we are unsuccessful in defending our treatment of intercompany

transactions, we may be subject to additional tax liability, interest, or penalty, which could adversely affect our profitability **and operating cash flow** . ~~In October 2019~~ **On November 6** , **2023,** we **, as borrower,** and certain of our ~~wholly- owned~~ subsidiaries ~~(collectively~~ , **as guarantors,** ~~the " Borrowers ")~~ entered into a **Financing** ~~Second Amended and Restated Credit~~ Agreement (the " **Financing** ~~Amended Credit~~ Agreement ") **with Blue Torch Finance LLC, as administrative agent and collateral agent, and certain lenders party thereto** . The **Financing** ~~Amended Credit~~ Agreement provides for a $ ~~300~~ **100** . 0 million **senior secured term loan (the " Initial Term Loan "), a $ 25. 0 million senior secured delayed draw term loan facility (the " Delayed Draw Term Loan "), and a $ 25. 0 million senior** secured revolving credit facility ~~maturing~~ **(the " Revolving Credit Facility, " and together with the Initial Term Loan and the Delayed Draw Term Loan, the " Credit Facilities "), each of which mature** on **November 6, 2027. In connection with entering into the Financing Agreement, we repaid in full amounts outstanding and terminated all commitments under our prior credit agreement (which had a maturity date of** October 25, 2024 **). The Initial Term Loan was fully funded on November 6** , ~~and amends and restates~~ **2023. As of** the ~~previous~~ **date of this filing (March 5, 2024), we had not made any borrowings under the Delayed Draw Term Loan, but had borrowed** $ ~~125~~ **15** . 0 million ~~secured~~ **under the Revolving Credit Facility. Borrowings under the Financing Agreement were and may be used for, among other things, (i) the repayment in full of amount that we had outstanding under our prior credit agreement, (ii) working capital and (iii) other general corporate purposes. Borrowings under the Credit Facilities bear interest at a floating rate, which will be, at our option, either the three-month SOFR rate (subject to a floor of 3. 00 % and a credit spread adjustment of 0. 26161 %) (the " Adjusted Term SOFR Rate ") plus an applicable margin of 7. 25 %, or a base rate plus an applicable margin of 6. 25 %. A revolving unused line fee of 2. 00 % is payable monthly in arrears based on the average amount of the undrawn portion of each lender' s** revolving credit **commitments under the Revolving Credit** ~~facility~~ **Facility for the preceding month** . ~~No~~ **A delayed draw unused fee equal to the Adjusted Term SOFR Rate plus a margin of 1. 00 % is payable monthly in arrears based on the average** amount ~~is currently outstanding on the credit facility as~~ of ~~December 31, 2022, or as of~~ the ~~date hereof, but we may~~ **undrawn portion of each lender' s delayed** draw ~~on this facility~~ **term loan commitments** in **respect of** the **Delayed Draw Term Loan for the preceding month. Certain of our existing and** future **material** ~~. Certain of our~~ subsidiaries (collectively, the " Guarantors ") are required to guarantee the repayment of ~~any~~ **our** obligations under the **Financing** ~~Amended Credit~~ Agreement. ~~The~~ **Our** obligations **and each of the Guarantors** with respect to the **Financing** ~~Amended Credit~~ Agreement are secured by a pledge of substantially all of **our** ~~the personal property~~ assets ~~of the Borrowers~~ and **the assets of** each of the Guarantors, including **, without limitation,** accounts receivables, deposit accounts, intellectual property, investment property, ~~and~~ inventory, equipment, and equity interests in their respective subsidiaries. The **Financing** ~~Amended Credit~~ Agreement contains customary affirmative and negative covenants, including limitations on our **and our subsidiaries'** ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness, and enter into affiliate transactions. In addition, the **Financing** ~~Amended Credit~~ Agreement contains financial covenants requiring us to maintain ~~, on~~ a **minimum level of liquidity at all times, a maximum** consolidated ~~basis as of the last day of any fiscal quarter, a total net~~ leverage ratio ~~of not more than 3. 5 to 1. 0~~ (**measured on a** ~~which ratio can be permitted to increase to 4. 0 to 1. 0 for no more than 4 fiscal quarters~~ **quarterly basis** ~~following a material acquisition~~) ~~and~~ **,** ~~an~~ **and** ~~interest~~ **a minimum asset** coverage ratio **(measured on a monthly basis)** ~~of at least 3. 0 to 1. 0~~ . The **Financing** ~~Amended Credit~~ Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the ~~facility~~ **Credit Facilities** may be accelerated and / or the lenders' commitments terminated. We believe that we ~~are~~ **will be** in compliance with the covenants ~~, and there were no events of default, at December 31, 2022 (and~~ in ~~prior periods)~~ **future fiscal quarters** . However, there can be no assurance that we will be **in** ~~able to meet~~ such ~~financial covenants in future fiscal quarters. The~~ **compliance, and if we are not, the** failure to do so could result in an event of default ~~under such agreement~~ , which could have a material adverse effect on our financial position in the event that we **continue to** have significant amounts drawn under the facility at such time. We must maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows. Because we maintain substantial inventory levels to meet the needs of our customers, we are subject to the risk of inventory excess, obsolescence **,** and shelf- life expiration. Many of our spinal implant products come in sets. Each set includes a significant number of components in various sizes so that the physician may select the appropriate spinal implant based on the patient' s needs. In a typical surgery, not all of the implants in the set are used, and therefore certain sizes of implants placed in the set or that we purchase for replenishment inventory may become obsolete before they can be used. In addition, to market our products effectively, we often must provide hospitals and independent sales agents with consigned sets that typically consist of spinal implants and instruments, including products to ensure redundancy and products of different sizes. Further, our biologics products have expiration dates, which range from one to five years, and these products may expire before they can be used. If a substantial portion of our inventory is deemed excess, becomes obsolete, or expires, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Further, as we increasingly launch new products and product systems, we may cannibalize older products and product systems, which could exacerbate excess and obsolete charges. We may need additional financing in the future to meet our capital needs or to make opportunistic acquisitions, and such financing may not be available on favorable terms, if at all. We may need additional financing in the future to meet our capital needs or to make opportunistic acquisitions. The capital and credit markets may experience extreme volatility and disruption, which may lead to uncertainty and liquidity issues for both borrowers and investors, and we may be unable to obtain any desired additional financing on favorable terms, if at all. If adequate funds are not available to us on acceptable terms, we may be unable to successfully develop or enhance products, or respond to competitive pressures, any of which could negatively affect our business, results of operations **,** and financial condition. If we raise capital by issuing debt or entering into credit facilities, we

may be subject to limitations on our operations due to restrictive covenants **. We hold our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail. We hold our cash and cash equivalents used to meet our working capital and operating expense needs in deposit accounts at multiple financial institutions. The balance held in these accounts typically exceeds the Federal Deposit Insurance Corporation (" FDIC") standard deposit insurance limit or similar government guarantee schemes. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short- term liquidity and ability to meet our operating expense obligations. For example, on March 10, 2023, Silicon Valley Bank (" SVB"), and Signature Bank, were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the United States Department of Treasury, the Federal Reserve, and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner** . General Risks Our stock price has fluctuated and may continue to fluctuate, which may make future prices of our stock difficult to predict. Investors should not rely on recent or historical trends to predict future stock prices, financial condition, results of operations, or cash flows. Our stock price, like that of other medical device companies, can be volatile and can be affected by, among other things: speculation, coverage, or sentiment in the media or the investment community; the announcement of new, planned or contemplated products, services, technological innovations, acquisitions, divestitures, or other significant transactions by us or our competitors; our quarterly financial results and comparisons to estimates by the investment community or financial outlook provided by us; the financial results and business strategies of our competitors; publication of research reports about us or our industry or changes in recommendations or withdrawal of research coverage by securities analysts; changes in laws or regulations affecting our business, including tax legislation; changes in accounting standards, policies, guidance, interpretations **,** or principles; threatened or actual litigation or governmental investigations; and inflation; market volatility or downturns caused by outbreaks, epidemics, pandemics, geopolitical tensions or conflicts, or other macroeconomic dynamics. General or industry specific market conditions or stock market performance or domestic or international macroeconomic and geopolitical factors unrelated to our performance also may affect the price of our stock. In addition, the stock market in general, and the stocks of medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. This could limit or prevent investors from readily selling their shares and may otherwise negatively affect the liquidity of our common stock. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company' s securities. This litigation, if instituted against us, could result in very substantial costs, divert our management' s attention and resources, and harm our business, financial condition **,** and results of ~~operation~~ **operations** . We expend substantial resources to comply with laws and regulations relating to public companies, and any failure to maintain compliance could subject us to regulatory scrutiny and cause investors to lose confidence in our company, which could harm our business and have a material adverse effect on our stock price. Laws and regulations affecting public companies, including provisions of the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 and the Sarbanes- Oxley Act of 2002, and the related rules and regulations adopted by the SEC, and by the Nasdaq Stock Market increase our accounting, legal **,** and financial compliance costs and make some activities more time- consuming and costly. We cannot predict or estimate with any reasonable accuracy the total amount or timing of the costs we may incur to comply with these laws and regulations. We are also subject to SEC regulations that require us to determine whether our products contain certain specified minerals, referred to under the regulations as " conflict minerals, " and, if so, to perform an extensive inquiry into our supply chain, to determine whether such conflict minerals originate from the Democratic Republic of Congo or an adjoining country. Compliance with these regulations has increased our costs and has been time- consuming for our management and our supply chain personnel (and time- consuming for our suppliers), and we expect that continued compliance will continue to require significant money and time. In addition, to the extent any of our disclosures are perceived by the market to be " negative, " it may cause customers to refuse to purchase our products. Further, if we determine to make any changes to products, processes, or sources of supply, it may result in additional costs, which may adversely affect our business, financial condition **,** and results of operations. Our amended and restated bylaws designates certain courts as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Our amended and restated bylaws ~~provides~~ **provide** that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by applicable law: (A) the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, the Superior Court of the State of Delaware, or, if both the Court of Chancery of the State of Delaware and the Superior Court of the State of Delaware lack subject matter jurisdiction, the United States District Court for the District of Delaware) and any state (or, if applicable, federal) appellate court therefrom shall be the sole and exclusive forum for (i) any derivative action, suit, or proceeding brought on behalf of our company, (ii) any action, suit, or proceeding asserting a claim of breach of fiduciary duty owed by any current or former director, officer, or other employee, or stockholder of ours to our company or our stockholders or any action asserting a claim for aiding and abetting any such breach of fiduciary duty, (iii) any action, suit, or proceeding asserting a claim against us or any of our directors, officers, or other employees arising pursuant to, or seeking to enforce any right, obligation, or remedy under, any provision of the General Corporation Law of Delaware (the " DGCL ") or our (certificate of incorporation or bylaws, (iv) any action, suit, or proceeding as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (v) any action, suit, or proceeding asserting a claim against us

or our current or former directors, officers, employees, or stockholders governed by the internal affairs doctrine, in all cases subject to the court' s having personal jurisdiction over the indispensable parties named as defendants (including personal jurisdiction by reason of any such indispensable party' s consent to personal jurisdiction in the State of Delaware or such court); and (B) the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. These provisions may limit a stockholder' s ability to obtain a judicial forum that such stockholder may prefer for disputes governed by these provisions. Environmental, social, and corporate governance (" ESG ") regulations, policies and provisions may make our supply chain more complex and may adversely affect our relationships with customers. There is an increasing focus on the governance of environmental and social risks. A number of our customers who are payors or distributors have adopted, or may adopt, procurement policies that include ESG provisions that their suppliers or manufacturers must comply with, or they may seek to include such provisions in their terms and conditions. An increasing number of participants in the medical device industry are also joining voluntary ESG groups or organizations, such as the Responsible Business Alliance. These ESG provisions and initiatives are subject to change, can be unpredictable, and may be difficult and expensive for us to comply with, given the complexity of our supply chain and the outsourced manufacturing of certain components of our products. If we are unable to comply, or are unable to cause our suppliers to comply, with such policies or provisions, a customer may stop purchasing products from us, and may take legal action against us, which could harm our reputation, revenue, and results of operations. Our business could be negatively impacted by corporate citizenship and ESG matters and / or our reporting of such matters. There is an increasing focus from certain investors, customers, consumers, and other stakeholders concerning corporate citizenship and sustainability matters. We could be perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.