

Risk Factors Comparison 2025-02-26 to 2024-02-27 Form: 10-K

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

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained or incorporated by reference in this Annual Report on Form 10-K. The risks and uncertainties described below are not the only risks faced by the Company. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial may become important factors that affect us. If any of such risks or the risks described below occur, either alone or taken together occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business and Industry Our business plan relies on certain assumptions pertaining to the market for our products that, if incorrect, may adversely affect our growth and profitability. We allocate resources based on assumptions about trends in the development of and treatment for spine disorders and the resulting demand for our products. Our assumptions may not be accurate. Increasing awareness and use of non-invasive treatments and other shifts in technologies and treatments, emergence of new materials and acceptance of emerging technologies and procedures could adversely affect demand for our products. If our assumptions prove to be incorrect or if alternative treatments to those we offer gain further acceptance, then demand for our products could be significantly less than we anticipate and we may not be able to achieve or sustain growth or profitability. We operate in a highly competitive market segment, face competition from large, well-established medical device companies with significant resources, and may not be able to compete effectively. The market in which we operate is highly competitive, subject to rapid technological change and affected by new products and market activities of industry participants. Our competitors include numerous large and well-capitalized companies such as Medtronic Sofamor Danek, a subsidiary of Medtronic; Depuy Spine, a subsidiary of Johnson & Johnson; Stryker; Zimmer Biomet; and Globus Medical. Several of our competitors enjoy competitive advantages over us, including:

- more established relationships with healthcare providers, distribution networks and healthcare payers;
- broader product offerings and intellectual property portfolios, better name recognition, and more recognizable product trademarks;
- greater resources for product research and development, clinical data, patent litigation, and launching, marketing, distributing and selling our products; and
- greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements.

In addition, at any time our current competitors or new industry participants may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products, including ones that may be superior to our spine surgery products. For these reasons, we may not be able to compete successfully against our existing or potential competitors. Any such failure could lead us to further modify our strategy, lower our prices, increase our sales commissions and could have a significant adverse effect on our business, financial condition and results of operations. A significant percentage of our revenues are derived from sales of our systems that include polyaxial pedicle screws. Net sales of our systems that include polyaxial pedicle screws represented approximately **40 % and 41 %** ~~and 42 %~~ our net sales for the years ended December 31, **2024 and 2023** ~~and 2022~~, respectively, and are expected to continue to be significant in the future. A decline in sales of these systems for any reason would have a significant adverse impact on our business, financial condition and results of operations. We rely on third-party licenses related to our polyaxial pedicle screw systems in order to use various proprietary technologies that are material to these systems, including the enforceability of the intellectual property rights in such technologies. Certain of our licenses may be terminated upon specific conditions. Our rights under each of the licenses are subject to our continued compliance with the terms of the license, including certain diligence, disclosure and confidentiality obligations and the payment of royalties and other fees. Because of the complexity of our product and the patents we have licensed, determining the scope of the license and related obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license or termination of the license. Any action that would prevent us from manufacturing, marketing and selling these systems or increase the costs associated with these systems would have a significant adverse effect on our business, financial condition and results of operations. Our reliance on sales agents could affect our ability to market our products efficiently and profitably. The development of a large distribution network may be expensive and time consuming. Because of the intense competition for their services, we may be unable to recruit or retain qualified independent sales agents. Like us, some of our competitors enter into exclusive distribution agreements. Further, we may not be able to enter into agreements with independent sales agents on commercially reasonable terms. Even if we do enter into agreements with new independent sales agents, it may take 90 to 120 days or even longer for new sales agents to reach full operational effectiveness. Some sales agents may not generate revenue as quickly as we expect, may not commit the necessary resources to effectively market and sell our products and may not ultimately be successful in selling our products. Our business, financial condition and results of operations will be materially adversely affected if we do not attract and retain new sales agents or if the marketing and sales efforts of our sales agents are unsuccessful. To be commercially successful, we must convince the spine surgeon community that our products are an attractive alternative to competitive products. In order for us to sell our products, spine surgeons must be convinced that our products are superior to competing products. Acceptance of our products depends on educating the spine surgeon community as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of our products compared to competitive products and on training spine surgeons in the proper application of our products. If we are not successful in convincing the spine surgeon community of the merit of our products, our sales will decline, and we will be unable to increase or achieve and sustain growth or profitability. Additionally, if surgeons 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, any of which could have a significant adverse effect on our business, financial condition and results of operations. We rely on a limited number of third parties to manufacture and supply our products. Any problems experienced by these manufacturers could result in a delay or interruption in the supply of our products until such manufacturer cures the problem or until we locate and qualify an alternative source of supply. We rely on third party manufacturers of our implants, instruments, imaging equipment and spare parts. We currently rely on a limited number of third parties and any prolonged disruption in the operations of our third- party suppliers could have a negative impact on our ability to supply products to customers. We may suffer losses as a result of business interruptions that exceed coverage under our manufacturer' s insurance policies. Other events beyond our control could also disrupt our product development and commercialization efforts until such events can be resolved or we can put in place third- party contract manufacturers to assume this manufacturing role. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. Delays associated with the verification of a new manufacturer or the re- verification of an existing manufacturer could negatively affect our ability to develop products or supply products to customers in a timely manner. Any disruption in the manufacture of our products by our third- party suppliers could have a material adverse impact on our business, financial condition and results of operations. We depend on third- party suppliers, and in one case a single supplier, for key raw materials and the loss of any of these third- party suppliers, or their inability to supply us with adequate raw materials, could harm our business. We rely on a number of suppliers and in one case on a single source vendor, Invibio, to provide the raw materials used in the production of our products. We have a supply agreement with Invibio, pursuant to which it supplies us with PEEK, a biocompatible plastic that we use in some of our spacers. Invibio is one of a limited number of companies approved to distribute PEEK in the U. S. for use in implantable devices. We depend on a limited number of sources of human tissue for use in our biologics products. Our supply of human tissue from our current suppliers and our current inventory of biologics products may not be available at current levels or may not be sufficient to meet our needs. Our dependence on a single third- party PEEK supplier and the challenges we may face in obtaining adequate supplies of biologics products involve several risks, including limited control over pricing, availability, quality and delivery schedules. Any supply interruption in a limited or sole sourced component or raw material could materially harm our ability to source manufactured products until a new source of supply could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have a significant adverse effect on our business, financial condition and results of operations. If we or our suppliers fail to comply with applicable regulations, the manufacture of our products could be delayed. We and our suppliers are subject to extensive regulation by the FDA and other regulatory agencies both inside and outside of the U. S. The FDA, and other regulatory agencies, audit compliance with some of these regulations. If significant non- compliance issues arise or if a corrective action plan is not sufficient, the manufacture or sale of our products may be limited until such problems are corrected to the regulatory body' s satisfaction, which could have a material adverse effect on our business, financial condition and results of operations. Further, our products could be subject to recall if the regulatory body determines, for any reason, that our products are not safe or effective. Any recall or additional regulatory approval or clearance requirements could result in delays, costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the regulatory body, all of which could have a material adverse effect on our business, financial condition and results of operations. Demand for our products, and prices at which customers and patients are willing to pay for our products depend upon the ability of our customers to obtain adequate third- party coverage and reimbursement product purchases. Sales of our products depend in part on the availability of adequate coverage and reimbursement from third- party payers, principally Medicare, Medicaid and private health insurance plans, to pay for all or a portion of the costs and fees associated with the use of our products. While procedures using our currently marketed products are eligible for reimbursement in the U. S., if surgical procedures utilizing our products are performed on an outpatient basis, it is possible that private payers may no longer provide reimbursement for the procedures using our products without further supporting data on the procedure. Any delays in obtaining, or an inability to obtain, adequate coverage or reimbursement for procedures using our products could significantly affect the acceptance of our products and have a significant adverse effect on our business. Additionally, third- party payers continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. Our business would be negatively impacted if there are any changes that reduce reimbursement for our products. Operation of our business internationally is subject to our continued compliance with the laws and regulations of each country in which we operate, as well as the business and legal customs in those jurisdictions and geographies. Our operations, both inside and outside the U. S., are subject to risks inherent in conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. Our operations outside the U. S. are subject to special risks and restrictions, including, without limitation: fluctuations in currency values and foreign- currency exchange rates; exchange control regulations; changes in local political or economic conditions; governmental pricing directives; import and trade restrictions; import or export licensing requirements and trade policy; restrictions on the ability to repatriate funds; and other potentially detrimental domestic and foreign governmental practices or policies affecting U. S. companies doing business abroad, including the U. S. Foreign Corrupt Practices Act and the trade sanctions laws and regulations administered by the U. S. Department of the Treasury' s Office of Foreign Assets Control. Acts of terror or war may impair our ability to operate in particular countries or regions and may impede the flow of goods and services between countries. Customers in weakened economies may be unable to purchase our products, or it could become more expensive for them to purchase imported products in their local currency, or sell at competitive prices, and we may be unable to collect receivables from such customers. Further, changes in exchange rates may affect our net earnings, the book value of our assets outside the U. S. and our stockholders' equity. Failure to comply with the laws and regulations that affect our global operations could have an adverse effect on our business, financial condition, or results

of operations. We may fail to realize the anticipated benefits of the Valence Transaction, as defined below. The success of our acquisition of Valence (the "Valence Transaction") will depend on, among other things, our ability to incorporate Valence into our business in a manner that enhances our value proposition to clients and facilitates other growth opportunities. If we are unable to successfully achieve these objectives, the anticipated benefits of the Valence Transaction may not be realized fully, if at all, or may take longer to realize than expected. Additionally, management may face challenges in incorporating certain elements and functions of Valence with our business, and this process may result in additional and unforeseen expenses. The integration of Valence Transaction may also disrupt our ongoing business or cause inconsistencies in standards, controls, procedures and policies that adversely affect our relationships with third party partners, employees, suppliers, customers and others with whom we or the business related to Valence have business or other dealings or limit our ability to achieve the anticipated benefits of the Valence Transaction. If we are unable to successfully integrate Valence into our existing business in an efficient, effective and timely manner, anticipated benefits, including the opportunities for expected growth from the Valence Transaction, may not be realized fully, if at all, or may take longer to realize than expected, and our cash flow and financial condition may be negatively affected.

Consolidation in the healthcare industry could lead to price concessions or exclusion of some suppliers from some markets, which could have an adverse effect on our business, financial condition or results of operations. Continued consolidation in the healthcare industry is expected to increase competition among providers of products and services to industry participants. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as GPOs, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to impact the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or results of operations. We may be subject to or otherwise affected by federal and state healthcare laws, including fraud and abuse, health information privacy and security, and disclosure laws, and could face substantial penalties if we are unable to fully comply with such laws. Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from any third-party payers for our products or the procedures in which our products are used, healthcare regulation significantly impacts our business. Healthcare fraud and abuse, health information privacy and security, and disclosure laws potentially applicable to our operations include:

- the federal Anti-Kickback Statute, as well as state analogs, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or providing remuneration, intended to induce the purchase or recommendation of an item or service reimbursable under a federal (or state or commercial) healthcare program (such as the Medicare or Medicaid programs);
- federal and state bans on physician self-referrals, which prohibits, subject to exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain "designated health services" if the physician or its immediate family member has any financial relationship with the entity;
- false claims laws that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- HIPAA, and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the state and federal laws "sunshine" provisions that require detailed reporting and disclosures to the CMS and applicable states of any payments or "transfer of value" made or distributed to prescribers and other health care providers, and for certain states prohibit some forms of these payments, require the adoption of marketing codes of conduct, require the reporting of marketing expenditures and pricing information and constrain relationships with physicians and other referral sources;
- the HITECH, which impose restrictions on uses and disclosures of protected health information and civil and criminal penalties for non-compliance and require the reporting of breaches to affected individuals, the government and in some cases the media in the event of a violation; and
- a variety of state-imposed privacy and data security laws which require the protection of personal information beyond health information and which require reporting to state officials in the event of breach or violation and which impose both civil and criminal penalties.

If our operations, or those of our independent sales agents violate any of such laws or any regulations that may apply to us, we may be subject to civil and criminal penalties, damages, fines, exclusion from federal healthcare programs and / or the curtailment or restructuring of our operations. If the healthcare providers, sales agents or other entities with which we do business are found to violate applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Sales and marketing practices in the healthcare industry have been the subject of increased scrutiny from governmental agencies, and we believe that this trend will continue. Prosecutorial scrutiny and governmental oversight over the retention of healthcare professionals as consultants has affected and may continue to affect how medical device companies retain healthcare professionals as consultants. Our efforts to detect and prevent noncompliance with applicable laws may not be effective in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If we fail to timely obtain governmental clearances or approvals for our future products or modifications to our products, our ability to commercially distribute and market our products could suffer. Our products are subject to extensive governmental regulations. The clearance and approval process, particularly with the FDA, can be costly and time consuming, and such clearances or approvals may not be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of most new medical devices only after receiving 510(k) clearance, or approval of a PMA. The FDA may make its 510(k) clearance process more restrictive and increase the time or expense required to obtain clearances or could make it unavailable for some of our products. A PMA must be submitted if the device cannot be cleared through the 510(k) process or is not exempt from

premarket review by the FDA and must be supported by extensive data, including results of preclinical studies and clinical trials, manufacturing and control data and proposed labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. The PMA process is more costly and uncertain than the 510 (k) clearance process. In addition, any modification to a 510 (k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510 (k) clearance or possibly a PMA. Commercial distribution and marketing of any of our products or product modifications will be delayed until regulatory clearance or approval is obtained which may take significantly longer than anticipated. Governmental authorities can delay, limit or deny clearance or approval of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the applicable regulatory authority that our products are safe or effective for their intended uses, or that the clinical and other benefits of the device outweigh the risks; • disagreement of the applicable regulatory authority with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials; • serious and unexpected adverse effects experienced by participants in our clinical trials; • data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; • our manufacturing process or facilities we use may not meet applicable requirements; or • approval policies or regulations of the applicable regulatory authorities change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval. Delays in obtaining regulatory clearances and approvals may delay or prevent commercialization of products we develop, require us to perform costly tests or studies, diminish any competitive advantages that we might otherwise have obtained and reduce our ability to generate revenues. If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or successfully integrate them in a cost-effective and non-disruptive manner. Our success depends in part on our ability to continually enhance and broaden our product offering. Accordingly, we have pursued and intend to pursue the acquisition of complementary businesses, products or technologies. We do not know if we will be able to successfully complete any acquisitions or successfully integrate any acquired business. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisition targets. These efforts could be expensive and time consuming, disrupt our ongoing business and distract management. If we are unable to integrate any future or recently acquired businesses, products or technologies effectively, our business, financial condition and results of operations will be materially adversely affected. We are dependent on our senior management team, sales and marketing team, engineering team and key surgeon advisors, and the loss of any of them could harm our business. Our continued success depends in part upon the continued availability and contributions of our senior management, sales and marketing team and engineering team and the continued participation of our key surgeon advisors. We compete for personnel and advisors with other companies and organizations, many of which have greater name recognition and resources than we do. Changes to our senior management team, sales and marketing team, engineering team and key surgeon advisors, or our inability to attract or retain other qualified personnel or advisors, could have a significant adverse effect on our business, financial condition and results of operations. Our business is dependent upon the effective operation of our information systems, software, or information security practices and those of our business partners or third-party service providers. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation. We utilize many information systems and other software that are critical to our business, some of which are managed by third parties. We regularly use these information systems or software to collect and store sensitive data, including legally protected patient health and personally identifiable information, intellectual property information, and proprietary business information. We may be unable to maintain or improve our information systems and software or experience unanticipated delays, complications, or expenses in implementing, integrating, and operating our systems or incur substantial expenditures or interruptions in operations in connection with system improvements or implementations. The failure of our information systems or software or those of our business partners or third-party service providers to perform properly could disrupt our business and harm our reputation, which may result in decreased sales, increased overhead costs, excess or obsolete inventory, and product shortages, causing our business, reputation, financial condition, and operating results to suffer. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to theft, loss, damage, and interruption from a number of potential sources and events, including unauthorized access or security breaches, data privacy breaches, natural or man-made disasters, cyber attacks, computer viruses, malware, phishing, denial of service attacks, power loss, or other disruptive events. Any such security incidents could compromise our networks and the information stored there could be accessed by unauthorized parties, disclosed, lost or stolen. Any such security incidents could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. Unauthorized access, loss or disclosure could also interrupt our operations and result in damage to our reputation, each of which could adversely affect our business. As a result of new SEC rules and regulations, we are required to disclose, on a current basis pursuant to new Item 1.05 of SEC Form 8-K, any cybersecurity incident that we determine to be material and describe the material aspects of the nature, scope, and timing of the incident, as well as the material impact or reasonably likely material impact of the incident on us, including our financial condition and results of operations. We will also be required to describe, on a periodic basis, our processes, if any, for the assessment, identification, and management of material risks from cybersecurity threats, and describe whether any risks from cybersecurity threats have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition, our board's oversight of risks from cybersecurity threats and management's role in assessing and managing material risks from cybersecurity threats. We have incurred significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event

of an actual or perceived security breach or incident and to comply with this new SEC cybersecurity rule. Additionally, our insurance policies may not be adequate to compensate us for the potential damages arising from any such disruption, failure or security breach or incident. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Nearly all of our operations are currently conducted in locations that may be at risk of damage from fire, earthquakes or other natural disasters. We conduct nearly all of our business activities in or near known wildfire areas and earthquake fault zones. We have taken precautions to safeguard our facilities, including obtaining property and casualty insurance, and implementing health and safety protocols. We have developed an information technology disaster recovery plan. However, any future natural disaster could cause substantial delays in our operations, damage or destroy our equipment or inventory and cause us to incur additional expenses. A disaster could seriously harm our business, financial condition and results of operations. Our insurance against earthquakes, fires, and other natural disasters would not be adequate to cover a total loss of our facilities, may not be adequate to cover our losses in any particular case and may not continue to be available to us on acceptable terms, or at all. Public health crises, political crises, and other catastrophic events or other events outside of our control may impact our business. A natural disaster (such as tsunami, power shortage, or flood), public health crisis (such as a pandemic or epidemic), political crisis (such as terrorism, war, political instability or other conflict), or other events outside of our control that may occur and may adversely impact our business and operating results. Moreover, these types of events could negatively impact surgeon or patient spending in the impacted region (s), which could adversely impact our operating results. We monitor such events and take actions that we deem reasonable given the circumstances. In the future other types of crises, may create an environment of business uncertainty around the world, which may hinder sales and / or supplies of our products nationally and internationally. Alphatec Holdings is a holding company with no operations, and unless it receives dividends or other payments from its subsidiaries, it will be unable to fulfill its cash obligations. As a holding company with no business operations, Alphatec Holdings' material assets consist only of the common stock of its subsidiaries, dividends and other payments received from time to time from its subsidiaries, and the proceeds raised from the sale of debt and equity securities. Alphatec Holdings' subsidiaries are legally distinct from Alphatec Holdings and have no obligation, contingent or otherwise, to make funds available to Alphatec Holdings. Alphatec Holdings will have to rely upon dividends and other payments from its subsidiaries to generate the funds necessary to fulfill its cash obligations. Alphatec Holdings may not be able to access cash generated by its subsidiaries in order to fulfill cash commitments. The ability of Alphatec Spine, SafeOp, or EOS to make dividend and other payments to Alphatec Holdings is subject to the availability of funds after taking into account its subsidiaries' funding requirements, the terms of its subsidiaries' indebtedness and applicable state laws. If we fail to properly manage our anticipated growth, our business could suffer. While we intend to continue to pursue growth in our business, such anticipated growth is expected to place significant demands on our managerial, operational and financial resources and systems. Our management may need to divert a disproportionate amount of its attention from day-to-day activities to managing these anticipated growth activities. If we do not manage our anticipated growth effectively, the quality of our products, our relationships with physicians, sales agents and hospitals, and our reputation could suffer, which would have a significant adverse effect on our business, financial condition and results of operations. **The use of artificial intelligence (" AI") technology by our employees or business partners could result in misuse or loss of proprietary information, violation of laws and regulations, or damage to our reputation and credibility. Our employees and business partners may use AI technology to perform their work. Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with use of AI technology. Additionally, the use and disclosure of personal data in AI technology is subject to various data privacy laws and other data privacy obligations. Governments have passed and are likely to pass additional laws regulating AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions and lawsuits. Further, the cost to comply with such laws or regulations, or decisions and / or guidance interpreting existing laws, could be significant and would increase our operating expenses, which could adversely affect our business, financial condition and results of operations.**

Risks Related to Our Financial Results, Credit and Certain Financial Obligations and Need for Financing We may need to raise additional funds in the future and such funds may not be available on acceptable terms, if at all. At December 31, ~~2023~~ **2024**, our principal sources of liquidity consisted of cash and cash equivalents of \$ ~~221.138~~ **0.8** million, accounts receivable, net, cash from operations and available borrowings under our revolving credit facility with entities affiliated with MidCap Financial Trust (" Revolving Credit Facility"). We believe that our current sources of liquidity will be sufficient to fund our planned expenditures and meet our obligations for at least 12 months subsequent to the date the consolidated financial statements are issued. If needed, we will seek additional funds from public and private equity or debt financings, borrowings under the Revolving Credit Facility, new debt facilities or other sources to fund our projected operating requirements. Our capital requirements will depend on many factors, including: • the revenues generated by sales of our products; • the costs associated with expanding our sales and marketing efforts; • the expenses that we incur from the manufacture of our products by third parties and that we incur from selling our products; • the costs of developing new products or technologies; • the cost of obtaining and maintaining FDA or other regulatory approval or clearance for our products and products in development; • the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights; • the number and timing of acquisitions and other strategic transactions; • the costs and any payments we may make related to our pending litigation matters; • the costs associated with increased capital expenditures; and • the costs associated with our employee retention programs and related benefits. As a result of these factors, we may need to raise additional funds and such funds may not be available on favorable terms, if at all. In addition, rules and regulations of the SEC may restrict our ability to conduct certain types of financing activities or may affect the timing of and the amounts we can raise by undertaking such activities. Furthermore, if we issue additional equity or debt securities to raise additional funds, our existing stockholders may experience dilution and the new equity or debt securities may

have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or to grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to repay debt or other liabilities, develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals and have a significant adverse effect on our business, financial condition and results of operations. Covenants in our loan documents and indenture may restrict our business and operations and if we do not effectively manage our covenants, our financial condition and results of operations could be adversely affected. The loan agreements we entered into in connection with our Revolving Credit Facility and the Braidwell Term Loan as well as the indenture governing our outstanding 0.75% Convertible Senior Notes due 2026 (the "2026 Notes") contain certain affirmative, operating or financial covenants. These covenants could adversely affect our ability to operate our business, our liquidity or our results of operations, and our inability to comply with any of these covenants could result in a default under the applicable loan agreement or indenture, which could result in an increase of the applicable interest rate or all amounts borrowed under the applicable debt instrument, together with accrued interest and other fees, to become due and payable or, with respect to our Revolving Credit Facility, could result in MidCap refusing to make further extensions of credit to ~~it~~ us. If our indebtedness under the Revolving Credit Facility, the Braidwell Term Loan or the 2026 Notes were to be accelerated, if the amount of interest owing under such debt or, in the case of the Revolving Credit Facility, if MidCap refuses to make further extensions of credit to us, we may not have sufficient cash available to repay the amounts due, and we may be forced to seek an amendment to the applicable loan terms or obtain alternative financing, which may not be available to us on acceptable terms, if at all. In addition, if we are unable to repay outstanding borrowings when due or upon an event of default, in the case of the Revolving Credit Facility and Braidwell Term Loan, the lender would also have the right to proceed against the collateral, including substantially all of our assets, granted to secure the indebtedness under the debt obligation. If the applicable lender proceeds against the collateral, such assets would no longer be available for use in our business, which would have a significant adverse effect on our business, financial condition and results of operations. We have a history of net losses, we expect to continue to incur net losses in the near future, and we may not achieve or maintain profitability. We have typically incurred net losses since our inception. As of December 31, ~~2023~~ 2024, we had an accumulated deficit of \$ 1.43 billion. We have incurred significant net losses since inception and have relied on our ability to fund our operations through revenues from the sale of our products and equity and debt financings. Successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure. This may not occur and, unless and until it does, we will continue to need to raise additional capital. We may seek additional funds from public and private equity or debt financings, borrowings under new debt facilities or other sources to fund our projected operating requirements. However, we may not be able to obtain further financing on reasonable terms or at all. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected. A significant economic downturn or volatility in the economy in any market in which we operate could have a material adverse impact on our business, financial condition, results of operations, or cash flows. As a result of our domestic and global business operations, our revenues are impacted by changes in domestic and global macroeconomic conditions. A weakening of economic conditions, including from a worsening of the ongoing labor shortage or rising in inflation, could lead to increased costs to our business and reductions in demand for our products. Weakened economic conditions or a recession could reduce the amounts that customers are willing or able to spend on our products. Furthermore, a high percentage of our expenses, including those related to inventory, capital investments, and operating costs are generally fixed in nature in the short term. If we are not able to timely and appropriately adapt to changes resulting from a weak or uncertain economic environment, our business, financial condition, results of operations and cash flows could be adversely impacted. Our quarterly financial results could fluctuate significantly. Our quarterly financial results are difficult to predict and may fluctuate significantly from period to period, particularly because our sales prospects are uncertain. The level of our revenues and results of operations at any given time will be based primarily on the following factors: • acceptance of our products by spine surgeons, patients, hospitals and third-party payers; • demand and pricing of our products, and the mix of our products sold, because profit margins differ among our products; • timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; • our ability to grow and maintain a productive sales and marketing organization and independent sales agent network; • regulatory approvals and legislative changes affecting the products we may offer or those of our competitors; • successful integration of newly acquired businesses, technology and personnel into our business operations; • the effect of competing technological and market developments; • levels of third-party reimbursement for our products; • interruption in the manufacturing or distribution of our products or our ability to produce or obtain products of satisfactory quality or in sufficient quantities to meet demand; and • changes in our ability to obtain FDA, state and international approval or clearance for our products. In addition, until we have a larger base of spine surgeons using our products, occasional fluctuations in the use of our products by individual surgeons or small groups of surgeons will have a proportionately larger impact on our revenues than for companies with a larger customer base. We cannot begin to commercialize any products that we seek to introduce in the U. S. without FDA approval or clearance. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. Any shortfalls in revenue or earnings from levels expected by our stockholders or by industry analysts could have a significant adverse effect on the trading price of our common stock in any given period. Risks Related to Our Intellectual Property, Regulatory Penalties and Litigation If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors and be unable to operate our business profitably. Our success depends significantly on our ability to protect our proprietary rights in the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and confidentiality and other contractual restrictions to protect our proprietary technology. These legal means

afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending patent applications may not result in issued patents. The U. S. Patent and Trademark Office (“PTO”) may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. Issued patents could subsequently be successfully challenged by others and invalidated or rendered unenforceable, which could limit our ability to prevent competitors from marketing and selling related products. In addition, our pending patent applications include claims to aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may design around our patents or develop products that provide outcomes that are comparable to our products but fall outside of the scope of our patent protection. Although we have entered into confidentiality agreements and intellectual property assignment agreements with certain of our employees, consultants and advisors as one of the ways we seek to protect our intellectual property and other proprietary technology, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. In the event a competitor infringes upon one of our patents or other intellectual property rights, enforcing those patents and rights may be difficult and time consuming. Even if successful, litigation to defend our patents against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management’s attention from managing our business. Moreover, we may not have sufficient resources to defend our patents against challenges or to enforce our intellectual property rights. The medical device industry is characterized by patent and other intellectual property litigation and we could become subject to litigation that could be costly, result in the diversion of management’s time and efforts, require us to pay damages, and / or prevent us from marketing our existing or future products. The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Determining whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that our products, components of those products, methods of using those products, or methods we employ to manufacture or process those products are covered by patents held by them. In addition, they may claim that their patents have priority over ours because their patents were filed first. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware, which may later result in issued patents that our products may infringe. There could also be existing patents that one or more components of our products may be inadvertently infringing, of which we are unaware. As the number of participants in the market for spine disorder devices and treatments increases, the possibility of patent infringement claims against us also increases. Any such claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If the relevant patents are upheld as valid and enforceable and we are found to infringe, we could be required to pay substantial damages and / or royalties and we could be prevented from selling our products unless we obtain a license or redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and we may be unable to redesign our products to not infringe those patents, and any such redesign, if possible, may be costly. If we fail to obtain any required licenses or make any necessary changes to our products, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, either of which could have a significant adverse effect on our business, financial condition and results of operations. We may lose market share to our competitors if we fail to protect our intellectual property rights. In addition, we enter into agreements with spine surgeons to develop new products. As consideration for product development activities rendered pursuant to these agreements, in some instances we have agreed to pay royalties on products developed by cooperative involvement between us and such surgeons. The surgeons with whom we have entered into such an arrangement might claim to be entitled to a royalty even if we do not believe that such products were developed by cooperative involvement between us and such surgeons. Any such claim, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage. Our business exposes us to potential product liability claims that are inherent in the manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including paralysis and even death. We carry product liability insurance. However, our product liability insurance coverage may be inadequate to satisfy liabilities we might incur. Any product liability claim brought against us could result in the increase of our product liability insurance rates or our inability to secure coverage in the future on commercially reasonable terms. If our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess out of our cash reserves, which could harm our financial condition. If longer- term patient results and experience indicate that our products or any component of our products cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and result in the diversion of management’s attention from managing our business. If a product liability claim or series of claims is brought against us in excess of our insurance coverage limits, our business could suffer and our financial condition, results of operations and cash flow could be materially adversely impacted. Because biologics products entail a potential risk of communicable disease to human recipients, we may be the subject of product liability claims regarding our biologics products. Our biologics products may expose us to additional potential product liability claims. The development of biologics products entails the risk of transmitting disease to human recipients, and substantial product liability claims may be asserted against us. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar

claims. Even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and result in the diversion of management's attention from managing our business. Any claims relating to our improper handling, storage or disposal of biological, hazardous and radioactive materials could be time consuming and costly. The manufacture of certain of our products, including our biologics products, involves the controlled use of biological, hazardous and / or radioactive materials and waste. Our business and facilities and those of our suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste. Although we believe that our safety procedures comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for damages or penalized with fines, which could exceed our resources and insurance. We may incur significant expenses in the future relating to any failure to comply with applicable laws and regulations, which could have a significant negative impact on our business, financial condition and results of operations. Risks Related to Our Common Stock Our stock price may fluctuate significantly, particularly if holders of substantial amounts of our stock attempt to sell, and holders may have difficulty selling their shares based on trading volumes of our stock. The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including those described elsewhere in this "Risk Factors" section and the following:

- volume and timing of orders for our products;
- quarterly variations in our or our competitors' results of operations;
- our announcement or our competitors' announcements regarding new or enhanced products, product enhancements, significant contracts, number of sales agents, number of hospitals and spine surgeons using products, acquisitions, and collaborative or strategic investments;
- announcements of technological or medical innovations for the treatment of spine pathology;
- changes in earnings estimates or recommendations by securities analysts;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- changes in healthcare policy in the U. S., including changes in governmental regulations or in the status of our regulatory approvals, clearances or applications, and changes in the availability of third-party reimbursement in the U. S.;
- product liability claims or other litigation involving us, including disputes or other developments with respect to intellectual property rights;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

We may become involved in securities class action litigation that could divert management's attention and harm our business. The stock market in general, the NASDAQ Global Select Market and the market for medical device companies in particular, has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. In the past, following periods of volatility in the market price of a particular company's securities, the company becomes subject to securities class action litigation. We may become involved in this type of litigation. Litigation is often expensive and diverts management's attention and resources, which could materially harm our financial condition, results of operations and business. Securities analysts may not provide coverage of our common stock or may issue negative reports, which may have a negative impact on the market price of our common stock. Securities analysts may not provide research coverage of our common stock. The trading market for our common stock may be affected in part by the research and reports that analysts publish about our business. If one or more of the analysts who elects to cover us downgrades our stock, our stock price could likely decline rapidly. If one or more of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. Because of their significant stock ownership, our executive officers, directors and principal stockholders will be able to exert control over us and our significant corporate decisions. Based on shares outstanding at February 19, 2024-2025, our executive officers, directors and stockholders holding more than 5 % of our outstanding common stock and their affiliates, in the aggregate, beneficially own approximately 30 % of our outstanding common stock. As a result, these persons will have the ability to impact significantly the outcome of all matters requiring stockholder approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership may harm the market price of our common stock by delaying, deferring or preventing our change in control, causing us to enter into transactions or agreements that are not in the best interests of all of our stockholders, or reducing our public float held by non-affiliates. Anti-takeover provisions in our organizational documents and change of control provisions in some of our employment agreements and agreements with sales agents, and in some of our outstanding debt agreements, as well as the terms of our redeemable preferred stock, may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely. Certain provisions of our amended and restated certificate of incorporation and restated by-laws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions:

- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- allow vacancies on our Board of Directors to be filled only by resolution of our Board of Directors;
- authorize our Board of Directors to issue, without stockholder approval, blank check preferred stock that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our Board of Directors and for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call stockholder meetings. These provisions may frustrate or prevent attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing our management. In addition,

because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15 % of our outstanding voting stock to merge or combine with us. Some of our agreements provide for accelerated vesting of benefits, including full vesting of restricted stock and options, upon a change of control, or extends the term of the agreement upon a change in control and make it more difficult for us or our successor to terminate the agreement. These provisions may discourage or prevent a change of control. In addition, in the event of a change of control, we would be required to redeem all outstanding shares of our redeemable preferred stock for an aggregate of \$ 29. 9 million, at the price of \$ 9. 00 per share. Further, our amended and restated certificate of incorporation permits us to issue additional shares of preferred stock. The terms of our redeemable preferred stock or any new preferred stock we may issue could have the effect of delaying, deterring or preventing a change in control. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ ownership change, ” generally defined as a cumulative change in its equity ownership by “ 5- percent shareholders ” of greater than 50 percentage points (by value) over a three- year period, the corporation’ s ability to use its pre- change net operating loss carryforwards (“ NOLs ”), and certain other pre- change tax attributes (such as research tax credits) to offset its post- change taxable income and taxes may be limited. We have completed multiple rounds of financing and entered into transactions which may subject us to the Section 382 limitations. We may also experience ownership changes in the future. As a result, our ability to use our NOLs and research and development credits to offset our U. S. federal taxable income and taxes may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, similar rules may also apply at the state level, and there may be periods during which the use of NOLs is suspended or limited, which could accelerate or permanently increase state taxes owed. We could be subject to changes in our tax rates, new tax legislation or additional tax liabilities. We are subject to taxes in the U. S. and foreign jurisdictions. Significant judgment is required to determine and estimate our worldwide tax liabilities. Due to economic and political conditions, tax rates in various jurisdictions may be subject to significant change. Our effective income tax rates have been, and could in the future be, adversely affected by changes in tax laws or interpretations of those tax laws; by stock- based compensation and other non- deductible expenses; by changes in the mix of earnings in countries with differing statutory tax rates; or by changes in the valuation of our deferred tax assets and liabilities. Our tax returns and other tax matters also are subject to examination by the U. S. Internal Revenue Service and other tax authorities and governmental bodies. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of our provision for taxes. We cannot guarantee the outcome of these examinations. If our effective tax rates were to increase, particularly in the U. S., or if the ultimate determination of our taxes owed is for an amount in excess of amounts previously accrued, our financial condition, operating results and cash flows could be adversely affected.