Risk Factors Comparison 2024-03-15 to 2023-03-16 Form: 10-K

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Our operating results and financial condition have varied in the past and could vary significantly in the future depending on a number of factors. You should consider carefully the risks and uncertainties described below, in addition to the other information contained in this Annual Report on Form 10- K, before deciding whether to purchase our common stock. If any of the following risks actually occur, our business, financial condition, results of operations, and future prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and stockholders could lose part or all of their investment. Risks Related to Our Business and Industry Our financial performance depends on sales growth and increasing demand for our legacy and acquired product portfolios, and we may not be able to successfully manage the recent, and future, expansion of our operations. Through our acquisitions of Parcus Medical and Arthrosurface in early 2020, we significantly broadened our technology and development platforms and commercialization infrastructure and expanded our addressable market from the global OA pain management market to the substantially larger global joint preservation market. Our future success depends on growth in sales of both our legacy and acquired products. There can be no assurance that such growth can be achieved or, if achieved, sustained. There can be no assurance that, even if substantial growth in product sales and the demand for our products is achieved, we will be able to: ● Gain acceptance of our broadened portfolio of existing products, as well as future products, by the medical community, hospitals, physicians, other health care providers, third- party payers, and end- users, which acceptance may depend upon the extent to which the medical community and end- users perceive our products as safer, more effective or more cost- competitive than other similar products. ● Maintain, manage, and develop the necessary manufacturing capabilities and inventory management practices; ● Develop, implement, and integrate the mix of appropriate sales channels needed to generate increased sales across our expanded product platform and to develop marketing partners and viable commercial strategies for the distribution of our expanded mix of products; ● Attract, retain, and integrate required key personnel; and ● Implement the financial, accounting, and management systems needed to manage our expanded business and growing demand for our products. There can be no assurance that our current and future products will achieve significant market acceptance on a timely basis, or at all. The failure of some or all of our products to achieve significant market acceptance, or our failure to successfully manage future growth, could have a material adverse effect on our business, financial condition, and results of operations. Substantial competition could materially affect our financial performance. We compete with many companies, including large pharmaceutical companies and large and specialized medical devices companies, across all our product lines. For our OA Pain Management products, our principal competitors include Sanofi Genzyme, Zimmer Biomet, Inc., Bioventus Inc., Avanos Medical, Inc., and Ferring Pharmaceuticals, as well as other companies that are commercializing or developing competitive products. Our key competitors for our Joint Preservation and Restoration products include Arthrex, Inc., the DePuy Synthes Companies of Johnson & Johnson, Smith & Nephew PLC., Stryker Corporation, and Zimmer Biomet, Inc., as well as certain smaller organizations that focus on subsets of the larger industry, such as Catalyst OrthoScience, Enovis Corporation and Shoulder Innovations. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations, and more experience in the regulatory process than us. We also compete with academic institutions, government agencies, and other research organizations that are involved in the research and development and commercialization of products similar to our own. Many of our competitors also compete against us in securing relationships with collaborators for their research and development and commercialization programs. Because a number of companies are developing or have developed products for similar applications as our products and have received FDA clearance or approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and / or obtain the FDA marketing and foreign regulatory clearance or approvals prior to our competitors, or, if regulatory clearance or approval is not obtained prior to our competitors, to identify markets for our products that may be sufficient to permit meaningful sales of our products. Additionally, legislation and regulation aimed at curbing rising healthcare costs has resulted in a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. In turn, this has led to greater and more intense competition in the provision of products and services to market participants. Important market makers, like group purchasing organizations and integrated delivery networks, have increased their negotiating leverage, and if these market makers demand significant price concessions or if we are excluded as a supplier by these market makers, our product revenue could be adversely impacted. There can be no assurance that we will be able to compete against current or future competitors or that competition will not have a material adverse effect on our business, financial condition, and results of operations. Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if we are excluded from being a supplier by a group purchasing organization or similar entity. Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators, and third- party payers to curb these costs. As a result, there has been a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and may continue to become more intense. This may result in greater pricing pressures and the exclusion of certain suppliers from important markets as group purchasing organizations, independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions. If a group purchasing organization excludes us from being one of their suppliers, 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 **and limit our access to sell our products and services to customers** . A significant portion of our OA Pain Management revenues are derived from a small number of customers, the loss of which could materially adversely affect our business, financial condition and results of operations. We have historically derived most of our ~~OA Pain Management~~ revenues from a small number of customers who resell our products to end- users. Many of these customers are significantly larger companies than us. In ~~2022~~ **2023** , Mitek **,** accounted for ~~43~~ **45** % of our ~~total~~ revenue. While we have started to diversify our sales channels, including through the implementation of a direct commercial model in the United States for our Joint Preservation and Restoration products, we expect to continue to be dependent on a small number of large customers for a substantial portion of our business. The failure of key customers to purchase our products in the amounts they historically have or in amounts that we expect would seriously harm our business. In addition, if present and future customers terminate their purchasing arrangements with us, significantly reduce or delay their orders, or seek to renegotiate their agreements on terms less favorable to us, our business, financial condition, and results of operations will be adversely affected. If we accept terms less favorable than the terms of the current agreements, such renegotiations may have a material adverse effect on our business, financial condition, and / or results of operations. Furthermore, in any future negotiations we may be subject to the perceived or actual leverage that these customers may have given their relative size and importance to us. Any termination, change, reduction, or delay in orders could seriously harm our business, financial condition, and results of operations. The loss of any one of our major customers, the delay of significant orders from such customers or our inability to timely supply product to these customers (including due to production and shipping delays attributable to supply or staffing shortages), even if only temporary, could reduce or delay our recognition of revenues, harm our reputation in the industry, and reduce our ability to accurately predict cash flow, and, as a consequence, could seriously harm our business, financial condition, and results of operations. We experience quarterly sales volume variation, which makes our future results difficult to predict and makes period- to- period comparisons potentially not meaningful. We experience quarterly fluctuations in our product sales as a result of multiple factors, many of which are outside of our control including our ~~arrangement~~ **arrangements** with Mitek which performs most of the downstream sales and marketing activities to customers and end- users for Monovisc and Orthovisc in the United States. Therefore, we are subject to fluctuations in our customers' sales patterns and corresponding ordering patterns, including Mitek. These quarterly fluctuations create uncertainty as to the volume of sales that we may achieve in a given period. As a result, comparing our operating results on a period- to- period basis might not be meaningful. You should not rely on our past results as an indication of our future performance. Our operating results could be disproportionately affected by a reduction in revenue because a proportionately smaller amount of our expenses varies with our revenue. As a result, our quarterly operating results are difficult to predict, even in the near term. We rely on a small number of suppliers for certain key raw materials and **components** ~~a small number of suppliers for a number of other materials required~~ for the manufacturing and delivery of our products, and disruption could materially adversely affect our business, financial condition, and results of operations. Although we believe that alternative sources for many of these and other components and raw materials that we use in our manufacturing processes are available, we cannot be certain that the supply of key raw materials will continue to be available at current levels or will be sufficient to meet our future needs. **We** ~~The COVID- 19 pandemic has impacted, and the lingering effects of the pandemic may~~ continue to **see** ~~impact~~ **impacts** ~~,~~ **on** our supply chain as the companies that produce our products, product components or otherwise support our manufacturing processes, the distribution centers where we manage our inventory, or the operations of our logistics and other service providers, including third parties that sterilize and store our products, **were** ~~are, or may be~~ disrupted, temporarily closed or ~~experience~~ **experienced** worker shortages for a sustained period of time **during and following the global pandemic or due to other supply chain disruptions** . For example, for the manufacture of Arthrosurface joint solutions products, we engage a single third- party organization as a contract manufacturer. This contract manufacturer has noted that there could be lead times up to a year or more to deliver ~~certain products~~ **product** . Any supply interruption could harm our ability to manufacture our products until a new source of supply is identified and qualified. We may not be able to find sufficient alternative suppliers in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired. Our manufacturing processes involve inherent risks, and disruption could materially adversely affect our business, financial condition, and results of operations. The operation of biomedical manufacturing plants involves many risks, including the risks of breakdown, failure, substandard performance of equipment, the inability of production runs to pass internal quality standards, the need to comply with the requirements of directives of government agencies, including the FDA, and the occurrence of natural and other disasters. Such occurrences could have a material adverse effect on our business, financial condition, and results of operations during the period of such operational difficulties and beyond. We could become subject to product liability claims, which, if successful, could materially adversely affect our business, financial condition, and results of operations. The testing, marketing, and sale of human health care products include an inherent risk of allegations of product liability, and there can be no assurance that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and we believe that we have adequate insurance coverage to cover such product liability claims should they arise, there can be no assurance that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition, and results of operations. Failure to comply with current or future national, international, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security, including restrictive European regulations, could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. We and our third- party providers are subject to national, international, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security. This

includes the European Union, or EU, GDPR, **and the United Kingdom, or UK, equivalent of the same (the UK GDPR, together with the EU GDPR, referred to as the GDPR),** as well as other national data protection legislation in force in relevant ~~EU~~ **European Economic Area, or EEA,** ~~member~~ **Member** ~~states~~ **States and the UK** (including ~~the GDPR in such form as incorporated into the law of England and Wales, Scotland and Northern Ireland by virtue of the European Union (Withdrawal) Act 2018 and any regulations thereunder and~~ the UK Data Protection Act 2018 **)** , **which governs the collection, use, storage, disclosure, transfer,** or **other processing of personal data (including health data processed in the context of clinical trials): (i) regarding individuals in the EEA and** UK ~~GDPR~~ **; and / or (ii) carried out in the context of the activities of our establishment in any EEA Member State or the UK** . The GDPR **is** ~~and UK GDPR are~~ wide- ranging in scope and ~~impose~~ **imposes** numerous additional requirements on companies that process personal data, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, requiring data protection impact assessments for high risk processing and requiring that certain measures (including contractual requirements) are put in place when engaging third- party processors. The GDPR ~~and the UK GDPR~~ also provide individuals with various rights in respect of their personal data. The GDPR ~~and UK GDPR define~~ **defines** personal data to include pseudonymized or coded data and requires different informed consent practices and more detailed notices for clinical trial participants and investigators than applies to clinical trials conducted in the United States. We are required to apply GDPR ~~and UK GDPR~~ standards to any clinical trials that our ~~EU~~ **EEA** and UK established businesses carry out anywhere in the world. Significantly, the GDPR ~~and the UK GDPR~~ impose strict rules on the transfer of personal data out of the ~~EU~~ **EEA** or the UK to the U. S. or other regions that have not been deemed to offer " adequate " privacy protections. Currently, we rely mainly on Standard Contractual Clauses approved by the European Commission, or SCCs, to legitimize transfers of personal data out of the ~~EU~~ **EEA** and International Transfer Agreements approved ~~in~~ the UK for transfers of personal data out of the UK, however, there continue to be concerns about whether the SCCs and other **international transfer** mechanisms will face additional legal challenges. Any inability to transfer personal data from the ~~EU~~ **EEA** to the U. S. in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position. The GDPR ~~and UK GDPR have increased~~ **increases** our responsibilities and may increase our liability in relation to personal data that we process where such processing is subject to the GDPR ~~and UK GDPR~~ . While we have taken steps to comply with the GDPR ~~and UK GDPR~~ , and implementing legislation in applicable ~~EU~~ **EEA** member states and the UK, including by seeking to establish appropriate lawful bases for the various processing activities we carry out, reviewing our security procedures and those of our service providers, and entering into data processing agreements with relevant service providers we cannot be certain that our efforts to achieve and remain in compliance have been, and / or will continue to be, fully successful. Given the breadth and depth of changes in data protection obligations, complying with the GDPR and ~~UK GDPR and~~ similar laws' requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third- party service providers, contractors or consultants that process or transfer personal data. **Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR, particularly with the UK plans to reform the country' s data protection legal framework in its Data Reform Bill introduced into the UK legislative process. In addition, EEA Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the GDPR and the competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance and could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA.** In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators and third- party providers. For example, California ~~has~~ enacted the California Consumer Privacy Act, or the CCPA **. This law** , which became effective on January 1, 2020 ~~. The CCPA~~ gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. ~~The CCPA~~ **It also** provides for civil penalties for violations, as well as a private right of action for data breaches that ~~is~~ **are** expected to increase data breach litigation. At this time, we do not collect personal data on residents of California but should we begin to do so, and in the context of doing so, become subject to the CCPA, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions. In addition ~~a California ballot initiative~~ , the California Privacy Rights Act, or CPRA, **which became effective on** ~~was passed in November 2020. As of~~ January 1, 2023, ~~the CPRA~~ imposes additional obligations on companies covered by the legislation and ~~will~~ significantly ~~modify~~ **modifies** the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also ~~creates~~ **created** a new state agency that **was** ~~will be~~ vested with authority to implement and enforce the CCPA ~~, as modified by the CPRA~~ . The effects of the CCPA are potentially significant and **, should we begin to process personal information concerning California residents** may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential

exposure to regulatory enforcement and / or litigation. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. New consumer privacy laws ~~enter into force~~ **similar to the CCPA have been passed** in **a number of states** ~~Connecticut, Colorado, Virginia~~ and ~~Utah in 2023. In addition,~~ many other states have proposed new privacy laws ~~, some of which are similar to the above discussed recently passed laws~~ . Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance **. In addition to these comprehensive laws and proposals, several other states have passed or proposed more limited privacy laws focused on particular privacy issues** . In addition, many jurisdictions around the world have adopted legislation that regulates how businesses operate online and enforces information security, including measures relating to privacy, data security and data breaches. Many of these laws require businesses to notify data breaches to the regulators and / or data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome. In many jurisdictions, enforcement actions and consequences for non- compliance with protection, privacy and information security laws and regulations are rising. In the ~~EU~~ **EEA** and the UK, data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to € 20 million (£ 17. 5 million in the UK) or 4 % of annual global revenue, whichever is greater. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non- compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws. In the United States, possible consequences for non- compliance include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. The risk of our being found in violation of these laws is increased by the fact that the interpretation and enforcement of them is not entirely clear ~~. EU Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the GDPR and the competent authorities in the EU Member States may interpret GDPR obligations slightly differently from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. In addition, the UK has announced plans to reform the country' s data protection legal framework in its Data Reform Bill, but these have been put on hold~~ . Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. It could also require us to change our business practices and put in place additional compliance mechanisms, which may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Failure by us or our and third- party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and orders preventing us from processing personal data), private litigation and result in significant fines and penalties against us. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects. We are increasingly dependent on sophisticated information technology and if we fail to effectively maintain or protect our information systems or data, including from data breaches, our business could be adversely affected. We are increasingly dependent on sophisticated information technology for our products and infrastructure. As a result of technology initiatives, recently enacted regulations, changes in our system platforms and integration of new business acquisitions, we have been consolidating and integrating the number of systems we operate and have upgraded and expanded our information systems capabilities. We also have outsourced elements of our operations to third parties, and, as a result, we manage a few third- party suppliers who may or could have access to our confidential intellectual property or business information. Our information systems, and those of third- party suppliers with whom we contract, 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 technology, evolving systems and regulatory standards and the increasing need to protect patient and customer information. In addition, given their size and complexity, these systems could be vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third- party suppliers and / or business partners, or from cyber- attacks by malicious third parties attempting to gain unauthorized access to our products, systems or Confidential Information. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial- of- service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. If such an event were to occur, it could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and result in a material disruption of our development programs and our

business operations. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our business, financial condition, results of operations and prospects. Likewise, we rely on third parties for various operations, including the manufacture of our products and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. Any breach in our or our third- party providers' information technology systems could lead to the unauthorized access, disclosure and use of non- public information, including protected health information and other personally identifiable information which is protected by HIPAA, and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our products could be delayed. If we or our third- party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third- party providers could have difficulty preventing, detecting and controlling such cyberattacks and any such attacks could result in losses described above as well as disputes with physicians, participants and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. Any compromise to our information security or that of our third **-** party service providers or contractors could result in an interruption in our operations, the unauthorized publication of our confidential business or proprietary information, the unauthorized release, use, disclosure and / or dissemination of customer, vendor, or employee data, the violation of privacy and / or data protection laws, including under the GDPR, in the European Union or the United Kingdom, or other laws and exposure to litigation, any of which could harm our business and operating results. We may face circumstances in the future that will result in impairment charges, including, but not limited to, goodwill impairment **, intangible assets impairment** and in- process research and development charges. As of December 31, ~~2022~~ **2023** , we had long- lived assets in the amount of $ ~~130~~ **58. 4 million, including property and equipment of $ 46** . 2 **million, intangible assets of $ 4. 6 million and goodwill of $ 7. 6** million. If the fair value of any of our long- lived assets, including those that we acquired in the acquisitions of Arthrosurface and Parcus Medical, decrease as a result of an economic slowdown, a downturn in the markets where we sell products and services, a downturn in our **stock price,** financial performance or future outlook, or other reasons, we may be required to record an impairment charge on such assets. We are required to test intangible assets with indefinite life periods for potential impairment annually and on an interim basis if there are indicators of a potential impairment. We also are required to evaluate amortizable intangible assets and fixed assets for impairment if there are indicators of a possible impairment. Impairment charges could have a negative impact on our results of operations and financial position, as well as on the market price of our common stock. **During the year ended December 31, 2023, we recorded an impairment charge of $ 62. 2 million on intangible assets related to the acquisitions of Arthrosurface and Parcus Medical.** Our business is dependent upon hiring and retaining qualified management, operations ~~, commercial~~ and technical personnel. We are highly dependent on the members of our management, operations ~~, commercial~~ and technical staff, the loss of one or more of whom could have a material adverse effect on us. We have experienced a number of management changes in recent years, and there can be no assurances that any future management changes will not adversely affect our business. We believe that our future success will depend in large part upon our ability to attract and retain technical and highly skilled executive, managerial, professional, and technical personnel. We **continue to engage with our employees on a regular basis to limit voluntary employee turnover. We** face significant competition for such personnel from competitive companies, research and academic institutions, government entities, and other organizations. There can be no assurance that we will be successful in hiring or retaining the personnel we require. The failure to hire and retain such personnel could have a material adverse effect on our business, financial condition, and results of operations. We may require additional capital in the future. We cannot give any assurance that such capital will be available at all or on terms acceptable to us, and if it is available, additional capital raised by us could dilute your ownership interest or the value of your shares. We may need to raise capital in the future depending on numerous factors, including: ● Market acceptance of our existing and future products; ● The success and sales of our products under various distributor agreements and other appropriate commercial strategies, including the ability of our partners to achieve third party reimbursement for our products; ● The successful commercialization of products in development through appropriate commercial models and marketing channels; ● Progress in our product development efforts; ● The magnitude and scope of such product development efforts; ● Any potential acquisitions of products, technologies, or businesses; ● Progress with preclinical studies, clinical trials, and product approvals and clearances by the FDA and other agencies; ● Requirement to conduct additional preclinical studies and clinical trials for future products; ● The cost and timing of our efforts to manage our manufacturing capabilities and related costs; ● **Expanding our manufacturing capacity to support growing demand for our products and add redundancies to our manufacturing process; ●** The cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights and the cost of defending any other legal proceeding; ● Competing technological and market developments; ● The development of strategic alliances for the marketing of certain of our products; ● The terms of such strategic alliances, including provisions (and our ability to satisfy such provisions) that provide upfront and / or milestone payments to us; ● The cost of maintaining adequate inventory levels to meet current and future product demand; and ● Further expanding our business in international markets. To the extent funds generated from our operations, together with our existing capital resources, are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, through strategic alliances with corporate partners and others, or through other sources. The

terms of any future equity financing may be dilutive to our investors and the terms of any debt financing may contain restrictive covenants, which limit our ability to pursue certain courses of action. Our ability to obtain financing is dependent on the status of our future business prospects as well as conditions prevailing in the relevant capital markets at the time, we seek financing. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise. If we succeed in raising additional funds through the issuance of equity or convertible securities, then the issuance could result in substantial dilution to existing stockholders. Furthermore, the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of common stock. In addition, any preferred equity issuance or debt financing that we may obtain in the future could have restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. Changes in tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local and non- U. S. taxation are constantly under review by persons involved in the legislative process, the Internal Revenue Service, the U. S. Treasury Department and other taxing authorities. Changes to tax laws or tax rulings, or changes in interpretations of existing laws (which changes may have retroactive application), could adversely affect us or the holders of our common stock. These changes could subject us to additional income- based taxes and non- income taxes (such as payroll, sales, use, value- added, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. **For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U. S. will be capitalized and amortized, which may have an adverse effect on our cash flow.** Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. As we expand the scale of our business activities, any changes in the U. S. and non- U. S. taxation of such activities may ~~increase~~ **impact** our effective tax rate **, result in higher tax payments** and harm our business, financial condition, **cash flows** and results of operations. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect the Company' s current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance **,** or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. If any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to lending arrangements with financial institutions, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: ● Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; ● Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and / or delays, inability or reductions in the company' s ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; ● Potential or actual breach of contractual obligations that require the Company to maintain letters of credit or other credit support arrangements; ● Potential or actual breach of financial covenants in our credit agreements or credit arrangements; ● Potential or actual cross- defaults in other credit agreements, credit arrangements or operating or financing agreements; or ● Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. Risks Related to Our Commercialization Activities Our license agreements with Mitek provide substantial control of Monovisc and Orthovisc in the United States to Mitek, and Mitek' s actions could have a material impact on our business, financial condition and results of operations. Our license and distribution agreements with Mitek related to Monovisc and Orthovisc provide Mitek with, among other things, the exclusive right to market and sell Monovisc and Orthovisc in the United States, unilateral decision- making authority over the sale, price, and promotion of Monovisc and Orthovisc in the United States, substantial control over the future development of Monovisc and Orthovisc related to the treatment of pain associated with osteoarthritis, a license to manufacture and have manufactured such products in the event that we are unable to supply Mitek with Monovisc or Orthovisc in accordance with the terms of the relevant agreement, and certain rights of first refusal with respect to future products we develop for the treatment of pain associated with osteoarthritis. In exchange, Mitek pays us a transfer price calculated with reference to historical end- user prices in the market and a fixed royalty rate per product on their net product sales. As Mitek accounts for a large percentage of our ~~yearly~~ revenue and has unilateral decision- making authority over in- market activities, including end- user pricing and discounts, reimbursement strategy, and overall promotion strategy, actions taken by Mitek could impact our ability to predict and generate revenue and have a material impact on our business,

financial condition, and results of operations. We may not succeed in our integration and buildout of our direct sales channel in the United States, and our failure to do so could negatively impact our business and financial results. Beginning in 2019, and with our expanded commercial infrastructure, as a result of the Parcus Medical and Arthrosurface acquisitions ~~in 2020~~, we ~~now sell~~ **sold and marketed** our Joint Preservation and Restoration family of products directly to customers, including hospitals and ASCs, through our direct Anika sales team and large network of independent third- party distributors. This approach was a departure from our historical distribution model in the United States, and we cannot be certain that we will be successful in implementing and executing on this commercial approach or that, even if we are able to implement it, the approach will be successful at scale. We may not be able to attract or retain the sophisticated personnel required for our approach, to identify or negotiate favorable or acceptable terms with distribution agents and ensure that they dedicate time and focus to our products, to achieve in- market pricing at the levels we have targeted, to develop and tailor our product portfolio to be specifically desired by clinicians who practice in ASCs, or to timely execute on our strategies for market penetration generally. Our failure to successfully implement and execute this commercial approach could have a material adverse effect on our business, financial condition, and results of operations. We are dependent upon marketing and distribution partners and the failure to maintain strategic alliances on acceptable terms will have a material adverse effect on our business, financial condition, and results of operations. Our success is dependent, in part, upon the efforts of our marketing, distribution, and logistics partners, including our sales agent partners in the United States, and the terms and conditions of our relationships with such partners. We cannot assure you that our commercial partners, including Mitek, will not seek to renegotiate their current agreements on terms less favorable to us or terminate such agreements. A failure to maintain relationships with our commercial partners on terms satisfactory to us, or at all, could result in a material adverse effect on our operating results. We continue to seek to establish long- term partnerships in regions and countries not covered by existing agreements, and we may need to obtain the assistance of additional marketing partners to bring new and existing products to market and to replace certain marketing partners. There can be no assurance that we will be able to identify or engage appropriate distribution or collaboration partners or effectively transition to any such new partnerships. The failure to establish strategic partnerships for the marketing and distribution of our products on acceptable terms and within our planned timeframes could have a material adverse effect on our business, financial condition, and results of operations. Sales of our products are largely dependent upon third- party health insurance coverage and reimbursement and our performance may be harmed by health care cost containment initiatives or decisions of individual third- party payers. In the United States and other foreign markets, health care providers, such as hospitals and physicians, that purchase health care products, such as our products, generally rely on third- party payers, including Medicare, Medicaid, and other health insurance and managed care plans, to provide coverage and to reimburse for all or part of the cost of the health care product or procedures that use such products. Coverage and reimbursement by third- party payers, both in the United States and internationally, may depend on several factors, including the individual payer' s determination that our products or procedures that use our products are clinically useful and cost- effective, medically necessary, and not experimental or investigational. Since insurance coverage determinations and reimbursement decisions are made by each payer individually, seeking positive coverage and reimbursement decisions can be a time consuming and costly process, which could require us or our marketing partners to provide supporting scientific, clinical, and cost- effectiveness data for the use of our products to each payer separately. Significant uncertainty exists as to the insurance coverage and reimbursement status of newly approved health care products or procedures that use such products, and any failure or delay in obtaining reimbursement approvals can negatively impact sales of our new products. In addition, we cannot be certain that payers who currently provide reimbursement for our products or procedures that use our products will continue to provide such reimbursement in the future, and such payer decisions could negatively impact the sales of our current or future products. In addition, third - party payers are increasingly attempting to contain the costs of health care products and services by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA, or the applicable foreign regulatory agency, has granted marketing approval. Also, the U. S. Congress, certain state legislatures, and certain foreign governments and regulatory agencies have considered reforms, including, among other items, any material changes to the ACA or the potential repeal of reference drug pricing in the United States, which may affect current reimbursement practices and create additional uncertainty about the pricing of our products, including the potential implementation of controls on health care spending through limitations on the growth of Medicare and Medicaid spending. For example, in 2010, the ACA was enacted and was intended to expand access to health insurance coverage and improve the quality of health care over time. There has been ongoing litigation and congressional efforts to modify or repeal all or certain provisions of the ACA. There may be uncertainties that result from modification or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business . There can be no assurance that third - party coverage will be available or that reimbursement will be adequate for any products or services developed by us or procedures using our products or services. Outside the United States, the success of our products is also dependent in part upon the availability of reimbursement and health care payment systems. Domestic and international reimbursement laws and regulations may change from time to time. Lack of adequate coverage and reimbursement provided by governments and other third- party payers for our products and services, including continuing coverage for Monovisc and Orthovisc in the United States, and any change of classification by the Centers for Medicare and Medicaid Services for reimbursement of Orthovisc and Monovisc, could have a material adverse effect on our business, financial condition, and results of operations. Risks Related to Our Product Development and Regulatory Compliance We are facing a longer than expected pathway to commercialize our Cingal product in the United States, and we may face other unforeseen difficulties in achieving regulatory approval for Cingal, which could affect our business and financial results. In 2018, we received and analyzed the results of our second Phase III clinical trial for

Cingal and found that the data did not meet the primary study endpoint of demonstrating a statistically significant difference in pain reduction between Cingal and the approved steroid component of Cingal at the six- month time point. After discussions ~~,~~ **with** the FDA ~~indicated~~ **, it was determined** that an additional Phase III clinical trial would **most likely** be necessary to support U. S. marketing approval for Cingal. In 2019, we began the design of our third Phase III clinical trial to enable us to evaluate our full- scale Phase III clinical trial design, including patient and site selection criteria, and increase the probability of success for the Phase III trial. In ~~2020 the first patient was enrolled in the pilot study and in~~ 2022, we completed this third Phase III clinical trial, which achieved its primary endpoint. Together with previous clinical studies, Cingal has demonstrated superiority over each of its active ingredients and placebo over 26 weeks for long- acting pain relief. We ~~will engage~~ **have been engaging** with the FDA ~~in the first half of 2023~~ on next steps for U. S. regulatory approval. In parallel, we are exploring the potential to advance Cingal through commercial partnerships in the U. S. and select Asian markets. These efforts will inform next steps, including if and how to proceed with another clinical trial in the United States. We cannot guarantee the success of any additional future clinical trials for Cingal. Because the results of any additional clinical trials, or other unforeseen future developments, could have a substantial negative impact on the timeline for and the cost associated with a potential Cingal regulatory approval, our overall business condition, financial results, and competitive position could be affected. **We also are conducting our clinical trial to support approval in the United States for Hyalofast, our single- stage, off- the- shelf, cartilage repair therapy, currently sold only outside the United States. We have fully enrolled the 200 patients targeted in the trial. This pivotal trial has a two- year follow- up protocol expected to be achieved in early 2025 before regulatory submission is completed. We are targeting to file the first module as part of a modular PMA in 2024 which is the first step in seeking FDA approval for Hyalofast in the U. S. The final module of the PMA will be filed in 2025 once the clinical data becomes available to be submitted to the FDA.** Failure to obtain, or any delay in obtaining, FDA or other U. S. and foreign governmental clearances or approvals for our products may have a material adverse effect on our business, financial condition **,** and results of operations. Several of our current products under development, and certain future products we may develop, will require clinical trials to determine their safety and efficacy for marketing approval by regulatory bodies, including the FDA. Product development and clearance or approval within the FDA and international regulatory frameworks takes several years and involves the expenditure of substantial resources. There can be no assurance that the FDA or other regulatory authorities will accept submissions related to our new products or the expansion of the indications of our current products, and, even if submissions are accepted, there can be no guarantee that the FDA or other regulatory authorities will grant clearance or approval for our new products, on a timely basis, if at all. In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local, and foreign regulations applicable to product clearance or approval, which may vary significantly across jurisdictions. Additional clearance or approval of existing products may be required when changes to such products may affect the safety and effectiveness, including for new indications for use, labeling changes, process or manufacturing changes, the use of a different facility to manufacture, process or package the product, and changes in performance or design specifications. For our devices that are subject to 510 (k) clearances, the FDA requires device manufacturers to make a determination of whether a modification requires a clearance; however, the FDA can review a manufacturer' s decision not to submit for additional clearances. We cannot provide any assurance that the FDA will agree with our decisions not to seek clearances for particular device modifications. If the FDA disagrees, and requires new clearances or approvals for any modifications, and we fail to obtain such approvals or clearances or fail to secure approvals or clearances in a timely manner, we may be required to recall and to stop the manufacturing and marketing of the modified device until we obtain the FDA approval or clearance, and we may be subject to significant regulatory fines or penalties. Failure to obtain regulatory clearance or approvals of our products, including any changes to existing products, could have an adverse material impact on our business, financial condition, and results of operations. Even if ultimately granted, the FDA and international regulatory clearances or approvals may be subject to significant, unanticipated delays throughout the regulatory review process. Internally, we make assumptions regarding product clearance or approval timelines, both in the United States and internationally, in our business planning, and any delay in clearance or approval could materially affect our competitive position in the relevant product market and our projections related to future business results. We cannot be certain that product clearance or approvals, both in the United States and internationally, will not include significant limitations on the product indications, and other claims sought for use, under which the products may be marketed. The relevant approval or clearance may also include other significant conditions such as post- market testing, tracking, or surveillance requirements. Any of these factors could significantly impact our competitive position in relation to such products and could have a negative impact on the sales of such products. Once obtained, we cannot guarantee that the FDA or international product clearances or approvals will not be withdrawn or that relevant agencies will not require other corrective action, and any withdrawal or corrective action could materially affect our business and financial results. Once obtained, marketing approval can be withdrawn by the FDA or comparable foreign regulatory agencies for a number of reasons, including the failure to comply with ongoing regulatory requirements or the occurrence of unforeseen problems following initial approval. Regulatory authorities could also limit or prevent the manufacture or distribution of our products. Any regulatory limitations on the use of our products or any withdrawal or suspension of approval or rescission of approval or reclassification by the FDA or a comparable foreign regulatory agency could have a material adverse effect on our business, financial condition, and results of operations. Our operations and products are subject to extensive regulation, compliance with which is costly and time consuming, and our failure to comply may result in substantial penalties, including recalls of our products. The FDA and foreign regulatory bodies impose extensive regulations applicable to our operations and products, including regulations governing product and sterilization standards, packaging requirements, labeling requirements, adverse event reporting, quality system and manufacturing requirements, import restrictions, tariff regulations, duties, and tax requirements. The FDA and other foreign regulatory bodies worldwide conduct periodic inspections of our facilities to determine compliance with the FDA' s requirements and all comparable foreign

regulations. We cannot assure you that we will be able to achieve and maintain compliance required for the FDA, CE marking, or other foreign regulatory clearances or approvals for any or all our operations and products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements. Failure to comply with applicable regulatory requirements could result in substantial penalties, including warning letters, fines, injunctions, civil penalties, seizure of products, total or partial suspension of production, refusal to grant pre- market clearance or pre- market approval for devices or drugs, withdrawal of approvals, and criminal prosecution. Additionally, regulatory authorities have the power to require the recall of our products. It also might be necessary for us, in applicable circumstances, to initiate a voluntary recall per regulatory requirements of one or several of our products. The imposition of any of the foregoing penalties, whether voluntarily or involuntary, could have a material negative impact on our business, financial condition, and results of operations. Any changes in the FDA or international regulations related to product approval or approval renewal, including those currently under consideration by the FDA or those that apply retroactively, could adversely affect our competitive position and materially affect our business and financial results. The FDA and foreign regulations depend heavily on administrative interpretation, and we cannot assure you that future interpretations made by the FDA or other regulatory bodies, with possible retroactive effects, will not adversely affect us. Additionally, any changes, whether in interpretation or substance, in existing regulations or policies, or any future adoption of new regulations or policies by relevant regulatory bodies, could prevent or delay approval of our products. In the event our future, or current, products, including HA generally, are classified, or re- classified, as human drugs, combination products, or biologics by the FDA or an applicable international regulatory body, the applicable review process- related to such products is typically substantially longer and substantially more expensive than the review process to which they are currently subject as medical devices. In 2018, the FDA publicly indicated its intent to consider HA products for certain indications for regulation as a drug and has indicated that industry should submit new products or indication expansions to its Office of Combination Products to designate the appropriate FDA office for review. There exists uncertainty with respect to the final interpretation, implementation, and consequences of this development, and this or any other potential regulatory changes in approach or interpretation similar in substance to those mentioned in this paragraph and affecting our products could materially impact our competitive position, business, and financial results. Additionally, the implementation of the new EU MDR which was put into effect in 2021, has changed several aspects of the medical device regulatory framework in the EU. Specifically, the EU MDR requires (i) changes in the clinical evidence required for medical devices, (ii) post- market clinical follow- up evidence, (iii) annual reporting of safety information for Class III and Class IIb products, and reporting every two years for Class IIa products, (iv) Unique Device Identification, or UDI, for all products and submission of core data elements to an EU UDI database prior to placement of a device on the market, (v) reclassification of some medical devices, and (vi) multiple other labeling changes. Approvals for certain of our currently marketed products could be curtailed or withdrawn as a result of the implementation of the EU MDR, and acquiring approvals for new products could be more challenging and costly. The EU MDR requires all devices to undergo review and approval for compliance to EU MDR **by the expiry of a transitional period** . The original ~~compliance~~ **expiry** date of May 26, 2024 ~~is being reconsidered~~ **has been extended to December 2027 or December 2028 for certain devices, depending on the risk class of the device,** in response to concerns raised about notified body capacity and the ability for devices to be re- certified within ~~such~~ **the original** time period ~~. The European Commission' s proposal is to December 2027 or December 2028, depending on the risk class of the device. This proposal has been approved by the Council of the European Union, and is awaiting publication in the Official Journal to be made effective, which is expected to occur in March 2023~~ . We have reviewed our products that are sold in the EU market and have completed the product rationalization exercise to identify the products that we will continue to market in the EU. Products we intend to continue marketing will require substantial submissions to be made to the notified bodies **for a conformity assessment under the EU MDR** no later than May 26, 2024, for the MDR extension timelines to apply. Compliance with this and any other requirements is time consuming and costly, and our failure to comply may subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations. Notices of inspectional observations or deficiencies from the FDA or other regulatory bodies require us to undertake corrective and preventive actions or other actions to address the FDA' s or other regulatory bodies' concerns. These actions could be expensive and time- consuming to complete and could impose an additional burden on us. We are subject to periodic inspections by the FDA and other regulatory bodies related to regulatory requirements that apply to products designed and manufactured, and clinical trials sponsored, by us. If we receive a notice of inspectional observations or deficiencies from the FDA or other regulatory bodies following an inspection, we may be required to undertake corrective and protective actions or other actions in order to address the FDA or other regulatory bodies concerns which could be expensive and time- consuming to complete and could impose additional burdens and expenses. We have previously received notices of observations or deficiencies from the FDA. Failure to adequately address the FDA' s or other regulatory bodies' concerns could expose us to enforcement or administrative actions. We may rely on third parties to support certain aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory clearance or approval or commercialize our products, and our business could be substantially harmed. We have hired experienced clinical development and regulatory staff, and we have also retained the services of knowledgeable external service providers, including consultants and clinical research organizations, to develop and supervise our clinical trials and regulatory processes. Despite our internal investment in staffing, we will remain dependent upon these third- party contract research organizations and consultants to carry out portions of our clinical and preclinical research studies and regulatory filing assistance for the foreseeable future. As a result, we have had and will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events, and the management of data developed through the trials than would be the case if we were relying entirely on our own staff. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. Failure by these third parties to comply with regulatory

requirements or to meet timing expectations may require us to repeat clinical trials or preclinical studies, which would delay the regulatory clearance or approval process, or require substantial unexpected expenditures. If we are found to have improperly promoted our products for off- label uses, we may become subject to significant fines and other liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices and drugs. For example, devices cleared under section 510 (k) cannot be marketed for any intended use that is outside of the FDA' s substantial equivalence determination for such devices. Physicians nevertheless may use our products on their patients in a manner that is inconsistent with the intended use cleared by the FDA. If we are found to have promoted such " off- label " uses, we may become subject to significant government fines and other related liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. We are subject to various healthcare laws and regulations, and any failure to comply with applicable laws could subject us to significant liability and harm our business. The sales, marketing and pricing of products and the relationships that medical products companies have with healthcare providers such as physicians, hospitals, ASCs, and others are under increased scrutiny. Our industry is subject to various laws and regulations pertaining to healthcare fraud and abuse, as well as other laws that impose extensive tracking and reporting related to all transfers of value provided to certain health care providers and others. These laws include the False Claims Act, the Anti- Kickback Statute, the Stark law, the Physician Payments Sunshine Act, the FDCA, and similar laws and regulations in the U. S. and around the world. These laws and regulations are broad in scope and are subject to evolving interpretation. We could be required to incur substantial costs to investigate, audit, and monitor compliance or to alter our practices, to the extent that we are subject to government scrutiny under these laws. In addition, we are subject to various laws concerning anti- corruption and anti- bribery matters (including the Foreign Corrupt Practices Act), sales to countries or persons subject to economic sanctions and other matters affecting our international operations. Violations of these laws are punishable by criminal and / or civil sanctions, including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. These laws are administered by, among others, the U. S. Department of Justice, the U. S. Department of Health and Human Services Office of Inspector General, the Securities and Exchange Commission, the Office of Foreign Access Control, the Bureau of Industry and Security of the U. S. Department of Commerce, and state attorneys general. Any failure to comply with these laws could subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations. We are subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business. We are subject to a variety of local, state, federal, and foreign government regulations relating to the storage, discharge, handling, emission, generation, manufacture, and disposal of toxic or other hazardous substances used in the manufacture of our products. Any failure by us to control the use, disposal, removal, or storage of hazardous chemicals or toxic substances could subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations. Risks Related to Our Growth Initiatives We may have difficulty managing our growth. As a result of our activities, we have experienced substantial growth in the number of our employees, the scope of our product portfolio and pipeline, the size of our operating and financial systems, and the geographic area of our operations. This growth has resulted in increased responsibilities for our management. To manage our growth effectively, we must continue to expand our management team, attract, motivate and retain employees, and improve our operating and financial systems. There can be no assurance that our current management systems will be adequate or that we will be able to manage our recent or future growth successfully. Any failure to do so could have a material adverse effect on our business, operating results and financial condition. We may not generate the expected benefits of our acquisitions, and the ongoing integration of those acquisitions could disrupt our ongoing business, distract our management and increase our expenses. Through our acquisitions of Parcus Medical and Arthrosurface, we expanded our product portfolio and pipeline, diversified our business, expanded our commercial infrastructure, entered new markets, and increased the scope of our operations and the number of our employees. The continued successful integration of these other companies into our operations is critical to our future financial performance. This will require that we continue to integrate more closely the companies' product offerings and research and development capabilities, retain key employees, assimilate diverse corporate cultures, further integrate management and financial information systems, consolidate the acquired operations and manage geographically dispersed operations, among other things, each of which could pose significant challenges. The difficulty of combining the acquired companies with our company may be increased by the need to integrate personnel, and changes effected in the combination may cause key employees to leave. To succeed in the market for joint preservation and restoration, we must also invest additional resources, primarily in the areas of sales and marketing, to extend name recognition and increase market share. The integration of the two acquired companies into our operations has taken longer than originally anticipated and has required more effort and expense than was originally planned. This has resulted, and may continue to result, in the loss of valuable employees, additional expenses, the disruption of our ongoing business, processes and systems, or inconsistencies in standards, controls, procedures, practices, policies and compensation arrangements, any of which could adversely affect our ability to achieve the anticipated benefits of the acquisitions. There may be increased risk due to the ongoing integration of financial reporting and internal control systems. Any diversion of the attention of management created by the integration process, any disruptions or other difficulties encountered in the integration process, and unforeseen liabilities or unanticipated problems with the acquired businesses could have a material adverse effect on our business, operating results and financial condition. We are working diligently to complete integration activities, minimize employee disruptions and improve **production** ~~manufacturing and operations processes~~ and communication as we continue to integrate ~~the~~ Arthrosurface and Parcus Medical ~~businesses~~. It has been more challenging than anticipated to effectively and timely complete our integration goals. **The acquisition of these two companies and the related investment in**

the business have contributed to our net loss in recent years. We recorded an impairment to goodwill in 2020 and **to intangible assets in 2023 and** a reduction in the fair value of contingent consideration in connection with the acquisitions that was driven in part by **slower than expected revenue growth with** ~~the~~ **these businesses** ~~significant effect~~ that ~~COVID~~ **have impacted near** - **term cash flows** ~~19 has had on the business industry~~. There can be no assurance that these acquisitions will provide the benefits we expect or that we will be able to integrate and develop the operations of Parcus Medical and Arthrosurface successfully. Any failure to do so could have a material adverse effect on our business, operating results and financial condition. We expect to continue to actively explore inorganic growth as a part of our future growth strategy, which exposes us to a variety of risks that could adversely affect our business operations. Our business and future growth strategy includes as an important component the acquisition of businesses, technologies, services, assets or products that we believe are a strategic fit with or otherwise provide value to our business. We may fund these acquisitions by utilizing our cash, incurring debt, issuing additional shares of our common stock, or by other means. Completed transactions may expose us to a number of risks and expenses, including unanticipated liabilities, amortization expenses related to intangible assets with definite lives, or risks associated with entering new markets with which we have limited experience or where commercial alliances with experienced partners or existing sales channels are not available. Whether or not completed, transactions may result in diversion of management resources otherwise available for ongoing development of our business and significant expenditures. Customer and employee uncertainty about the effects of any acquisitions could harm us. Customers of any companies ~~or technologies that~~ we acquire may, in response to the consummation of the acquisitions, delay or defer purchasing decisions, which could adversely affect the success of our acquired businesses. Similarly, employees of acquired companies may experience uncertainty about their future roles, which may adversely affect our ability to attract and retain key management, sales, marketing, and technical personnel following an acquisition. As our international sales and operations grow, we could become increasingly subject to additional economic, political, and other risks that could harm our business. Since we manufacture our products for sale worldwide, our business is subject to risks associated with doing business internationally. During **2023,** 2022, **and** 2021, ~~and 2020~~ **26 %** , 24 %, **and** 23 ~~%, and 21~~ %, respectively, of our product sales were to international customers. We continue to be subject to a variety of risks, which could cause fluctuations in the results of our international and domestic operations. These risks include: ● The impact of recessions, inflation and other economic conditions in economies ~~, including the impact of the COVID- 19 pandemic,~~ outside the United States; ● Instability of foreign economic, political, and labor conditions; ● Fluctuations in foreign currency exchange rates relative to the U. S. dollar; ● Unfavorable labor regulations applicable to our European operations, such as severance and the unenforceability of non- competition agreements in the European Union; ● The impact of strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, or other collective bargaining disputes; ● Difficulties in complying with restrictions imposed by regulatory or market requirements, tariffs, or other trade barriers or by U. S. export laws; ● Imposition of government controls limiting the volume of international sales; ● Longer accounts receivable payment cycles; ● Potentially adverse tax consequences, including, if required or applicable, difficulties transferring funds generated in non- U. S. jurisdictions to the United States in a tax efficient manner; ● Difficulties in protecting intellectual property, especially in international jurisdictions; ● Difficulties in managing international operations; and ● Burdens of complying with a wide variety of foreign laws, including the EU MDR and GDPR among others. Our success depends, in part, on our ability to anticipate and address these and any new risks. We cannot guarantee that these or other factors will not adversely affect our business or operating results. Risks Related to Our Intellectual Property We may be unable to adequately protect our intellectual property rights, which could have a material impact on our business and future financial results. Our efforts to enforce our intellectual property rights may not be successful. We rely on a combination of copyright, trademark, patent, and trade secret laws, confidentiality procedures, and contractual provisions to protect our proprietary rights. Our success will depend, in part, on our ability to obtain and enforce patents and trademarks, to protect trade secrets, to obtain licenses to technology owned by third parties when necessary, and to conduct our business without infringing on the valid proprietary rights of others. The patent positions of pharmaceutical, medical product, and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that any patent applications will result in the issuance of patents or, if any patents are issued, that they will provide significant proprietary protection or commercial advantage or will not be circumvented by others. Filing and prosecution of patent applications, litigation to establish the validity and scope of patents, assertion of patent infringement claims against others, and the defense of patent infringement claims by others can be expensive and time consuming. There can be no assurance that, in the event that any claims with respect to any of our patents, if issued, are challenged by one or more third parties, any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation or patent review process could cause us to lose exclusivity covered by the disputed rights. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the technologies or marketing the products covered by such rights, we could be subject to significant liabilities to such third party, and we could be required to license technologies from such third party in order to continue production of the products. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology. We have a policy of seeking patent protection for patentable aspects of our proprietary technology. We intend to seek patent protection with respect to products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is appropriate. However, no assurance can be given that any patent application will be filed, that any filed applications will result in issued patents, or that any issued patents will provide us with a competitive advantage or will not be successfully challenged by third parties. The protections afforded by patents will depend upon their scope and validity, and others may be able to design around our patents. We also rely upon trade secrets and proprietary know- how for certain non- patented aspects of our technology. To protect such information, we have a policy requiring all employees, consultants, and licensees to enter into confidentiality

agreements limiting the disclosure and use of such information. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach, or that our trade secrets, proprietary know- how, and our technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology. There can be no assurance that we will not infringe upon the intellectual property rights of others, which could have a significant impact on our business and financial results. Other entities have filed patent applications for, or have been issued patents concerning, various products or processes in the segments in which we do business. There can be no assurance that the products or processes developed by us will not infringe on the patent rights of others in the future. The cost of defending infringement suits is typically large, and there is no guarantee that any future defense would be successful. In addition, infringement could lead to substantial damages payouts or our inability to produce or market certain of our current or future products. As a result, any such infringement may have a material adverse effect on our business, financial condition, and results of operations. Risks Related to the COVID- 19 Pandemic Our operations are located in areas impacted by the COVID- 19 pandemic, and those operations have been, and may continue to be, adversely affected by the COVID- 19 pandemic. The coronavirus has impacted the social and economic framework globally. Our administrative, research and development, and manufacturing operations are principally performed at our U. S. facilities in Massachusetts and Florida. Though our Italian operations represent a relatively small percentage of our consolidated business, we conduct commercial activity, product development, sales, logistics, inventory management and supply chain activities, and other services in our office in Padova, Italy. Our business operations in the United States and Italy are subject to potential business interruptions arising from protective measures that have been or may be taken by Italian, U. S., Massachusetts and Florida regulators and other government agencies due to COVID- 19 or its variants. Business disruptions elsewhere in the world could also negatively affect the sources and availability of components and materials that are essential to the operation of our business in both the United States and Italy. Our commercial day- to- day operations have been, and may in the future be, significantly impacted by cancellations or delays of elective procedures in hospitals and ASCs, and timelines associated with certain clinical studies and research and development programs have been delayed. Stay- at- home orders, business closures, travel restrictions, supply chain disruptions, employee illness or quarantines, our or our suppliers' ability to hire employees and other extended periods of interruption to our business have resulted in disruptions to our operations, caused us to cease or delay operations, and prevented our customers from receiving shipments or processing payments. All these impacts could continue as new variants of COVID- 19 could continue to impact our business. If a number of our essential employees become sick or otherwise unable to continue working during the current or any future epidemic, our operations may be harmed. Also, the remote work environment made necessary by the COVID- 19 pandemic may exacerbate various cybersecurity risks to our business, including an increased demand for information technology resources, an increased risk of phishing and other cybersecurity attacks, and an increased risk of unauthorized dissemination of sensitive personal information or proprietary or confidential information. Extended periods of interruption to our corporate, development or manufacturing facilities due to the COVID- 19 pandemic have caused or could cause us to lose revenue and market share, which has depressed and could continue to depress our financial performance and may be difficult to recapture. Employee disruptions and remote working environments related to the COVID- 19 pandemic have impacted, and are continuing to impact, the efficiency and pace with which we work and develop our product candidates and our manufacturing capabilities. In addition, the COVID- 19 pandemic and related economic uncertainties have increased challenges associated with hiring highly skilled and experienced employees and may continue to create challenges and / or adversely impact employee retention due to the additional financial, family, and health burdens that many employees or potential employees may be experiencing. Our industry' s highly competitive market for skilled workers and leaders may negatively affect our ability to retain qualified employees. Losing members of our senior management and other highly skilled personnel could prevent us from achieving our business objectives or divert management' s attention to seeking qualified replacements and ensuring seamless transitions. The COVID- 19 pandemic resulted in a significant reduction in the number of elective surgeries being performed since 2020 and the lingering impact of the pandemic has slowed the pace of new product approvals by current and potential customers, which has decreased the usage of, and revenue from, certain of our products. A significant portion of the demand for our products results from the usage of our products in elective surgeries. Since 2020, we have experienced a significant decline in procedure volume in the U. S. compared to previous levels, as healthcare systems diverted resources to meet the increasing demands of managing COVID- 19 and subsequently encountered significant staffing challenges when trying to support procedures. In addition, primarily as a result of the impacts of COVID- 19 including stay- at- home orders and other attempts to limit in- person meetings, and ongoing staffing challenges, hospitals and ASCs at times delayed having meetings of their committees to review and approve the introduction of new products into their facilities. As we are focused on growing our business by introducing new products to existing and new hospital and ASC customers, the inability to have our products timely reviewed and approved by these customers has also negatively impacted our revenue and operating results as delays in product approvals impact and draw out product adoption timelines. It is uncertain whether elective surgeries or product review and approval processes will be negatively impacted or halted again in the future by a resurgence of COVID- 19. The COVID- 19 pandemic, its variants or other similar pandemics could adversely impact our development activities, preclinical studies and clinical trials, which could significantly impair our long- term business plans and operating results. The timely initiation and completion of our preclinical and development activities and clinical trials depend upon the availability of facility access, preclinical study and clinical trial sites, researchers and investigators, regulatory agency personnel, and materials, all of which may be adversely affected by the COVID- 19 pandemic, its variants or other similar pandemics. The timing of our clinical trials depends on our ability to recruit patients to participate as well as the completion of required follow- up periods. The COVID- 19 pandemic has had and may continue to have a sustained impact on our ability to recruit, enroll, treat and follow- up with patients

either due to renewed restrictions on travel or shelter- in- place orders or policies, or due to changes in patient willingness to participate in trials or travel to study sites during a pandemic. The timeline for recruiting patients, conducting trials and obtaining regulatory approval of our product candidates have been and may in the future be delayed, which could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. Factors resulting from the COVID- 19 pandemic, its variants or other similar pandemics that could delay or otherwise adversely affect the completion of our preclinical activities and the planned activities related to our clinical trials, as well as our business generally, include: ● the potential diversion of healthcare resources away from the conduct of preclinical activities and clinical trials to focus on pandemic concerns, including the availability of necessary materials and the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials; ● limitations on travel that could interrupt key preclinical and clinical activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government- imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our research, manufacturing and clinical trial sites or secure visas or entry permissions, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials; ● interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact review, inspection, clearance and approval timelines; ● interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, product candidates and supplies, to be used in our prospective clinical trials; ● limitations on our business operations by government authorities that could impact our ability to conduct our preclinical or clinical activities; and ● business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees, manufacturing sites, research or clinical trial sites, and other important agencies and contractors. Our global supply chain may be materially adversely impacted due to the ongoing impacts of the COVID- 19 pandemic, its variants or other pandemics. We rely upon the facilities of our global suppliers to support our business. The COVID- 19 pandemic resulted in significant governmental measures being implemented in many countries to control the spread of COVID- 19, including restrictions on manufacturing and the movement of employees. As a result of COVID- 19 and the measures designed to contain its spread, certain of our suppliers did not have the materials, staffing, capacity, or capability to supply our needed materials and other supplies that we require to manufacture our products according to our schedule and specifications. It is uncertain whether and to what extent these supply chain challenges will continue or fully recover following the direct and indirect impacts of COVID- 19. Further, logistics issues, including our ability and our supply chain' s ability to quickly ramp up production, and transportation demands may cause delays. If our suppliers' operations are curtailed, we may need to seek alternate sources of supply, which may be more expensive or require approval from regulatory agencies which could cause further delays. Alternate sources may not be available or may result in delays in shipments to us from our supply chain and subsequently to our customers, each of which would affect our results of operations. If the duration of the production and supply chain disruptions continue for an extended period of time, the impact on our supply chain could have a material adverse effect on our results of operations and cash flows. Risks Related to Ownership of Our Common Stock Our stock price may be highly volatile, and we cannot assure you that market making in our common stock will continue. The market price of shares of our common stock may be highly volatile. Factors such as announcements of new commercial products or technological innovations by us or our competitors, disclosure of results of clinical testing or regulatory proceedings, government regulation and approvals, developments in patent or other proprietary rights, public concern as to the safety of products developed by us, and general market conditions may have a significant effect on the market price of our common stock. We have highlighted to investors increased volatility and uncertainty in the global macroeconomic environment and the changing dynamics associated with staffing shortages, supply chain disruption , **and** inflation and other direct and indirect impacts of the COVID pandemic . These actions, as well as general investor uncertainty, could create volatility and unpredictability in our stock price. The trading price of our common stock could also be subject to wide fluctuations in response to quarter- to- quarter variations in our operating results, material announcements by us or our competitors, governmental regulatory action, conditions in the health care industry generally or in the medical products industry specifically, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations, which have particularly affected the market prices of many medical products companies, and which often have been unrelated to the operating performance of such companies. Our operating results in future quarters may be below the expectations of equity research analysts and investors. In such an event, the price of our common stock would likely decline, perhaps substantially. Our charter documents contain anti- takeover provisions that may prevent or delay an acquisition of our company. Our charter documents contain anti- takeover provisions that could prevent or delay an acquisition of our company. The provisions include, among others, a classified board of directors, advance notice to the board of stockholder proposals, limitations on the ability of stockholders to remove directors and to call stockholder meetings, and a provision that allows vacancies on the Board of Directors to be filled by vote of a majority of the remaining directors. We are also subject to Section 203 of the Delaware General Corporate Law which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any " interested stockholder " for a period of three years following the date that such stockholder becomes an interested stockholder. Those provisions could have the effect of discouraging a third party from pursuing a non- negotiated takeover of our company at a price considered attractive by many stockholders and could have the effect of preventing or delaying a potential acquirer from acquiring control of our company. If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they adversely change their recommendations regarding our stock, our stock price and trading volume could

decline. The trading market for our common stock is influenced by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. No person is under any obligation to publish research or reports on us, and any person publishing research or reports on us may discontinue doing so at any time without notice. If adequate research coverage is not maintained on our company or if any of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business or provide relatively more favorable recommendations about our competitors, our stock price would likely decline. If any analysts who cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. We have been, and may continue to be, subject to the actions of activist stockholders, which could cause us to incur substantial costs, divert management' s and the board' s attention and resources, and have an adverse effect on our business and stock price. From time to time, we may be subject to proposals by activist stockholders urging us to take certain corporate actions or to nominate certain individuals to our board of directors. In February 2023, Caligan Partners LP, or Caligan, indicated that it ~~intends~~ **intended** to consider all available options, including nominating a slate of directors for election to the board of directors at our 2023 annual meeting of stockholders. **In April 2023, we entered into a Cooperation Agreement (the " Cooperation Agreement ") with Caligan. Pursuant to the Cooperation Agreement, we agreed to increase the size of our board of directors to eight directors and appointed Mr. Gary Fischetti as an independent Class III director. On March 6, 2024, Caligan nominated two directors for election to our board of directors at our 2024 annual meeting of stockholders.** If ~~activist stockholder activities, such as those by~~ Caligan **solicits proxies** ~~or~~ **for its candidates or proceeds with** other ~~stockholders, ensue~~ **similar types of actions** , our business could be adversely affected **.** ~~, as responding~~ **Responding** to **such** ~~proxy contests and reacting to other~~ actions by activist stockholders can be costly and time- consuming, disrupt our operations and divert the attention of management and our board of directors. For example, we have retained the services of various professionals to advise us on activist stockholder matters, including legal, financial, and communications advisors, the costs of which negatively impact our financial results and we may be required to retain additional services in the future, which could have a further negative impact on our financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, and employees, and cause our stock price to experience periods of volatility or stagnation.