Risk Factors Comparison 2024-03-22 to 2023-03-23 Form: 10-K

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You should carefully consider the following risks described below, together with all of the other information in this Annual Report, including our consolidated financial statements and related notes. While we believe that the risks and uncertainties described below are the material risks facing our business, additional risks that we do not know of or that we currently think are immaterial may also arise and materially affect our business. The realization of any of these risks could have a material adverse effect on our business, financial condition, results of operations, and our ability to accomplish our strategic objectives. Risks Related to Achieving or Sustaining Profitability, Financial Position and Capital Requirements We have incurred significant operating losses since inception, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability. We have incurred net losses since our incorporation on April 17, 2012. For the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , we had net losses of $ **46. 7 million, $** 44. 3 million ~~,~~ **and** $ 33. 3 million ~~and $ 28. 8 million~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~274~~ **320** . ~~2~~ **9** million. We expect to continue to incur significant sales and marketing, research and clinical development, regulatory and other expenses as we expand our sales and marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products, develop, acquire or license complimentary products for our product portfolio, or add new features to our existing products. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and may cause the market price of our common stock to decline. Our indebtedness may limit our flexibility in operating our business and adversely affect our financial health and competitive position. As of December 31, ~~2022~~ **2023** , we had $ 40. 0 million of indebtedness outstanding under our credit facility with MidCap Financial Trust (" MidCap ") that matures in May 2027. To service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory, and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness, our ability to plan for, or react to, changes in our business, industry and the economy generally will be limited. In addition, the MidCap credit facility contains certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests, including the incurrence of additional indebtedness, effecting certain corporate changes, making certain investments, acquisitions or dispositions and paying dividends. We have not previously breached and are not currently in breach of these or any of the other covenants; however, there can be no guarantee that we will not breach these covenants in the future. In the event that we breach one or more covenants, our lender may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations. We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. If needed, any future funding requirements will depend on many factors, including: ● surgeon and market acceptance of our products; ● the cost of our research and development activities; ● the cost and timing of obtaining regulatory clearances or approvals; ● the cost and timing of establishing additional sales and marketing capabilities; ● the cost and timing of clinical trials that we are currently conducting or may conduct in the future; ● costs associated with any product recall that may occur; ● the effect of competing products in our markets or competing technologies; ● the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions; ● the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights; and ● the cost of defending, in litigation or otherwise, any claims that we infringe third- party patents or other intellectual property rights. Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. In addition, any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third- parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third- parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations. If we are unable to expand, manage and maintain our direct sales and marketing organizations, we may not be able to generate anticipated revenue. Building the requisite sales, marketing and distribution capabilities to successfully

market and sell our products continues to be expensive and time- consuming and requires significant attention from our leadership team to manage. Any failure or delay in the expansion of our sales, marketing or distribution capabilities would adversely impact the commercialization of our products. Additionally, we may choose to collaborate, either globally or on a territory- by- territory basis, with third parties on the commercialization of our products. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products. As of December 31, ~~2022~~ **2023** , our commercial organization consisted of ~~123~~ **166** employees in the U. S. and ~~9~~ **14** employees in Europe. To generate future revenue growth, we plan to expand the size and geographic scope of our direct sales ~~39organization~~ **40organization** . This growth may require us to split or adjust existing sales territories, which may adversely affect our ability to retain customers in those territories. Additionally, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales and marketing personnel with significant industry experience and technical knowledge of medical devices and related products. The competition for talented individuals experienced in selling and marketing medical device products is intense, and we cannot assure you that we can assemble or maintain an effective team. We cannot assure you that we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Our operating results are directly dependent upon the sales and marketing efforts of our employees. Failure to hire or retain qualified sales and marketing personnel would prevent us from expanding our business and generating revenue. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products, which could have an adverse effect on our business, financial condition and results of operations. Macroeconomic conditions, including the ~~ongoing response to~~ **lingering economic effects of** the COVID- 19 pandemic **on hospital systems** , may negatively impact certain aspects of our business, our prospects, results of operations and financial condition. Macroeconomic conditions, including the **lingering economic effects of the** COVID- 19 pandemic, have negatively impacted our business, results of operations and financial condition, and, if ~~continued~~ **unresolved** or exacerbated by inflationary pressures, geopolitical conflict or other macroeconomic events, may adversely impact our business, financial condition and prospects. ~~In~~ **While** the ~~first quarter~~ **direct impact** of ~~2022, regional surges of the~~ COVID- 19 ~~Omicron variant resulted in some government restrictions on elective procedures and surgical staffing challenges leading to the deferral of elective surgeries. While the initial challenges from COVID- 19~~ and its variants **has largely** ~~have begun to subside~~ **subsided** , we cannot predict the severity of any long- term impact stemming from **financial and resource** strains on the healthcare system, labor and staffing in the hospital sector ~~,~~ ~~fatigue on healthcare workers~~ , and hospital capacity for elective procedures, that resulted from measures taken to address ~~the COVID- 19 pandemic. We do not know when, and how, hospitals will return to normal surgical procedural volumes and also reduce the substantial backlog in elective procedures deferred in response to~~ the COVID- 19 pandemic. Any prolonged delays in normalized levels of elective surgeries by governmental, hospital or payor actions would continue to impair net sales of our products. General supply chain disruptions, initially arising from COVID- 19, have ~~also~~ **in the wake of geopolitical turmoil, such as the ongoing Russia- Ukraine conflict and the current conflict in Israel and Gaza (including any escalation or expansion)** continued to ~~interrupt~~ **threaten** trade globally and ~~weakened~~ -- **weaken** supply systems. We currently rely on Aroa, which is headquartered in New Zealand, for supply of our products. While there have been minimal disruptions to our supply chain to date, there is a risk that in the future supplies of our products could be disrupted or delayed based on competition within **the** ~~a tightening~~ supply chain or otherwise affected by substantial inflationary pressures due to macroeconomic conditions. There can be no assurance that we would be able to timely implement any mitigation plans relating to our supply chain. Continued concerns about the systemic impact of potential **economic slowdown or** ~~long- term and wide- spread~~ recession, liquidity constraints, failures and instability in the U. S. and international financial banking systems, and geopolitical ~~issues~~ **turmoil** , including the ~~war in~~ **ongoing Russia-** Ukraine **conflict and the current conflict in Israel and Gaza (including any escalation or expansion)** , have contributed to increased market volatility and diminished expectations for economic growth in the world. These conditions may lead to continued volatility in the future, which could result in a decline in our stock price, high inflation, increase our cost of capital and adversely affect our ability to access the capital markets in the future even after local conditions improve. Market acceptance of our medical products in the U. S. and other countries is dependent upon the procurement practices of our customers, patient need for our products and procedures and the reimbursement of patients' medical expenses by government healthcare programs and third- party payors. The continuing uncertainty surrounding global economic conditions and financial markets, including the lingering economic impact of the COVID- 19 pandemic on our customers, may adversely affect demand for our products and procedures and result in lower reimbursement rates or coverage for our products, resulting in lower sales volume and downward pricing pressure on our products and slower adoption of new products. The full extent to which ~~the~~ **these** ~~global economic~~ **macroeconomic factors** ~~forces, including the COVID- 19 pandemic~~ , will further, directly or indirectly, impact our business, results of operations and financial condition, including our sales, expenses, manufacturing capability, supply chain integrity, research and development activities, and employee- related matters, will depend on future developments that are highly uncertain. ~~40Information~~ **41Information** pertaining to the impact of ~~the COVID- 19 pandemic and~~ these macroeconomic pressures on our operations to date can be found in " Management' s Discussion and Analysis of Financial Position and Results of Operations " in this Annual Report on Form 10- K. Rising inflation rates could negatively impact our revenues and profitability if increases in the prices of our product or a decrease in consumer spending results in lower volumes of elective surgeries. In addition, if our costs increase and we are not able to pass along these price increases, our profitability would be adversely affected, and the adverse impact may be material. Inflation rates, particularly in the U. S., have increased recently to levels not seen in years. Increased inflation may result in decreased demand for our products, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may ~~again~~ **in the future** raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and

heightening these risks. In an inflationary environment, we may be unable to raise the prices of our products at or above the rate at which our costs increase, which could / would reduce our profit margins and have a material adverse effect on our financial results. We also may experience lower than expected sales and potential adverse impacts on our competitive position if there is a decrease in consumer spending or a negative reaction to our pricing. A reduction in our revenue would be detrimental to our profitability and financial condition and could also have an adverse impact on our future growth. 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 our current and projected business operations and ~~its~~ financial condition and results of operations. 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. ~~Most recently~~ **For example** , **in early** ~~on March 10,~~ 2023, **several** ~~the California Department of Financial~~ **financial institutions** ~~Protection and Innovation~~ closed ~~Silicon Valley Bank (" SVB ")~~ and ~~appointed~~ **were taken into receivership by** the Federal Deposit Insurance Corporation ~~(" FDIC ") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder~~ . Even though 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 us, 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. ~~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 factors 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; ● Loss of access to working capital sources and / or the inability 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 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; or41 ● Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements.~~ In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations. ~~Risks~~ **42Risks** Related to the Commercialization of our ProductsTo date, the vast majority of our revenue has been generated from sales of our OviTex products, and we therefore are highly dependent on the commercial success of **the** OviTex product line. Sales of our OviTex products accounted for **67 %,** 70 % ~~,~~ **and** 78 ~~% and 83~~ % of total revenue for the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , respectively. We first commercialized OviTex products in the U. S. in 2016 and have **subsequently launched our OviTex products in Europe,** introduced our larger sized OviTex products, our OviTex LPR product for use in laparoscopic and robotic- assisted hernia surgical repairs ~~,~~ **and** larger configurations of our LPR product **. In addition to our OviTex products** , **we have also commercialized our** OviTex PRS products for use in surgery for soft- tissue repair or reinforcement in plastic and reconstructive procedures and **most** recently ~~our NIVIS Fibrillar Collagen Pack for~~ the ~~management of surgical wounds~~ **LiquiFix Hernia Mesh Fixation Devices (LiquiFix FIX8 ™ and LiquiFix Precision ™) pursuant to our distribution agreement with Advanced Medical Solutions Limited** . ~~We~~ **While we continue to diversify our portfolio and revenue sources, we** expect that sales of our OviTex products and our OviTex PRS products ~~,~~ will account for the majority of our revenue for the foreseeable future **while we continue to grow market share for our OviTex PRS products and other ancillary products that we may develop or distribute from time to time** . Our failure to successfully increase sales of these products or any other event impeding our ability to sell these products would result in a material adverse effect on our business, financial condition and results of operations. The commercial success of our products will largely depend upon attaining significant market acceptance. Our ability to execute our growth strategy, achieve commercial success and become profitable will depend upon the adoption by inpatient and outpatient hospitals, surgeons, and medical device supply chain participants of our reinforced tissue matrix products. We cannot predict how quickly, if at all, surgeons will accept our products or, if accepted, how frequently they will be used. Our products and planned or future products we may develop or market may never gain broad market acceptance among surgeons and the medical community for some or all of our indications. Some surgeons may have prior history with or a preference for other soft- tissue reinforcement products, such as permanent synthetic mesh, resorbable synthetic mesh, or other biologic matrices, or may be reluctant to alter their practice patterns to treat patients with our reinforced tissue matrix products. The degree of market acceptance of any of our products will depend on a number of factors, including: ●

whether surgeons and others in the medical community consider our products to be safe, effective and cost effective; ● the potential and perceived advantages of our products over alternative products; ● the effectiveness of our sales and marketing efforts for our products; ● the prevalence and severity of any complications associated with using our products; ● the convenience and ease of use of our products relative to competing products; ● product labeling or product insert requirements by regulatory authorities; ~~42~~ ● the competitive pricing of our products; ● the quality of our products meeting patient and surgeon expectations; ● the results of clinical trials and post- market clinical studies relating to the use of our products; ● pricing pressure, including from GPOs and government payors; ● the availability of coverage and adequate reimbursement for procedures using our products from third- party payors, including government authorities; **43** ● the willingness of patients to pay out- of- pocket for our products in the absence of coverage and adequate reimbursement by third- party payors, including government authorities; and ● our ability to provide incremental clinical and economic data that show the safety, clinical efficacy and cost effectiveness, and patient benefits from, our products. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies, which are more cost effective or received more favorably, are introduced. Failure to achieve or maintain market acceptance and / or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations. Even if we are able to attain significant market acceptance of our products, the commercial success of our products is not guaranteed. Our future financial success will depend substantially on our ability to effectively and profitably market and sell our products. Even if we are able to attain significant market acceptance of our products, the commercial success of our products and any of our planned or future products is dependent on a number of additional factors, including the results of clinical trials relating to the use of our products and our ability to obtain and maintain regulatory approval or clearance to market our products and maintain compliance with applicable regulatory requirements. Successful growth of our sales and marketing efforts will depend on the strength of our marketing and distribution infrastructure and the effectiveness of our marketing and sales efforts, including our efforts to expand our direct sales force, while our ability to satisfy demand for our products driven by our sales and marketing efforts will be largely dependent on the ability of Aroa to maintain a commercially viable manufacturing process that is compliant with regulatory standards. If we fail to successfully market and sell our products, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition and results of operations. Our ability to grow our revenue in future periods will depend on our ability to increase sales of our OviTex and OviTex PRS products and any new product or product indications that we introduce, which will, in turn, depend in part on our success in expanding our customer base and driving increased use of our products. New products or product indications may also need to be approved or cleared by the FDA and comparable non- U. S. regulatory agencies to drive revenue growth. If we cannot achieve revenue growth, it could have a material adverse effect on our business, financial condition and results of operations. The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of our products for these uses. Surgeons and other medical professionals may misuse our reinforced tissue matrix products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management' s attention from our core business, be expensive to defend ~~43and~~ -- **and** result in sizeable damage awards against us that may not be covered by insurance. In addition, any of the events described above could harm our business. The products we commercialize have been cleared by the FDA and other regulatory authorities for specific indications. Our OviTex products are reinforced tissue matrices designed for use as a surgical mesh to reinforce and / or repair soft- tissue where weakness exists and indications for use of our OviTex products include the repair of hernia and / or abdominal wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. Our OviTex PRS products are reconstructive reinforced tissue matrices designed for implantation to reinforce soft- tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. In connection with the March 2019 meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, the FDA stated that no surgical mesh device has been cleared or approved for use in breast surgery, and that to obtain such indication, the product sponsor must obtain an approved PMA. This statement applies to our OviTex PRS products as they are not cleared or approved for use in breast surgery and thus, we are prohibited from ~~marketing~~ **44marketing** them for that use. OviTex PRS or any other product we may develop for use in breast surgery will need to be approved specifically for that indication and there can be no guarantee that it will be approved. We have engaged in discussions with the FDA regarding an IDE protocol to study the safety and effectiveness of our OviTex PRS product for an indication in breast reconstruction surgery. There can be no assurance that we will be able to secure a PMA approval in a timely manner, or at all. Any marketing for OviTex PRS or any other product for a use in breast reconstruction surgery would be deemed off- label promotion of that product if it has been cleared for a general indication of use to reinforce or repair soft- tissue and has not received an approval specifically for use in breast surgery. We train our marketing personnel and direct sales force to not promote our OviTex or OviTex PRS products for uses outside of the FDA- cleared indications for use, known as " off- label uses. " We cannot, however, prevent a surgeon or medical professional from using our OviTex or OviTex PRS products or other products we may commercialize in the future for off- label uses. Although we train our direct sales force not to promote our products for off- label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared or approved for use, the FDA or another regulatory authority could conclude that we have engaged in off- label promotion. If the FDA determines that our promotional or training materials constitute promotion of an off- label use, or make claims that are not supported by the available clinical data, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or non- U. S. enforcement authorities might take action under other regulatory authority if they consider our business activities to constitute

promotion of an off- label use, or are otherwise objectionable, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. Even if surgeons or medical professionals use our OviTex **and OviTex PRS** products only for their approved indications, a failure by such surgeons and medical professionals to use our products in accordance with the processes and procedures established to properly utilize our OviTex **and OviTex PRS** products could result in product liability lawsuits, costly investigations and potentially affect our ability to achieve sufficient market penetration for our OviTex **and OviTex PRS** products. In those possible events, our reputation could be damaged and adoption of the products would be impaired. We may also be required to reassess the training, written instructions and product warnings or other labeling information we provide our customers. This process could require us to expend significant time and capital and could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business. If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our OviTex, OviTex PRS or other products we may commercialize in the future, our commercial success may be hindered. Our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third- party payors, including governmental payors (such as the Medicare and Medicaid programs in the U. S.), managed care organizations and private health insurers. The primary customers for our products are hospitals and ambulatory surgery centers who will then seek reimbursement from third- party payors for the procedures performed using our products. While some third- party payors currently cover and provide reimbursement for procedures using our currently cleared or approved products, we can give ~~44no~~ **no** assurance that these third- party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, to permit hospitals and surgeons to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using our products will continue. Additionally, no uniform policy for coverage and reimbursement exists in the U. S. and coverage and reimbursement can differ significantly from payor to payor. If third- party payors reverse or limit their coverage for the procedures using our currently cleared or approved products in the future, this could have a material adverse effect on our business. If we are forced to lower the price we charge for our products, this could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business. **See the section of this Annual Report titled " Coverage and Reimbursement " for more information.** Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives. Third- party payors, whether U. S. or non- U. S., or governmental or commercial, are developing increasingly ~~sophisticated~~ **45sophisticated** methods of controlling healthcare costs, including examining the cost effectiveness of procedures, in addition to their safety and efficacy, when making coverage and payment decisions. Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage or alter pre- authorization requirements for new or existing procedures. We cannot provide assurance that we will be successful in any efforts we may potentially undertake to reverse such non- coverage decisions. If we are not successful in reversing non- coverage policies, or if third- party payors that currently cover or reimburse certain procedures reverse or limit their coverage of such procedures in the future, or if other third- party payors issue similar policies, our business could be adversely impacted. Our long- term growth may depend on our ability to enhance our product offerings. It is important to our business that we continue to enhance our OviTex and OviTex PRS products and develop and introduce new reinforced tissue matrix products. Developing products is expensive and time- consuming and could divert management' s attention away from other aspects of our business. The success of any new reinforced tissue matrix product offering or product enhancements to our OviTex and OviTex PRS products will depend on several factors, including our ability to: ● properly identify and anticipate surgeon and patient needs; ● develop and introduce new products and product enhancements in a timely manner; ● avoid infringing upon the intellectual property rights of third parties; ● ensure the quality, manufacture and supply of new products by Aroa; ● demonstrate, if required, the safety and efficacy of new products with data from preclinical studies, clinical trials and post- market clinical studies; ● obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications; ● be fully FDA- compliant with marketing of new devices or products; ● provide adequate training to potential users of our new products; ● receive adequate coverage and reimbursement for procedures performed with our new products; and ● develop and expand an effective and dedicated sales and marketing team. If we are not successful in introducing new product indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. ~~45In~~ **In** the future our products may become obsolete, which would negatively affect operations and financial condition. The medical device industry is characterized by rapid and significant change. There can be no assurance that other companies will not succeed in developing or marketing devices and products that are more effective than our reinforced tissue matrix products or that would render our reinforced tissue matrix products obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. Accordingly, our success will depend in part on our ability to respond quickly to medical and other changes through the development and introduction of new products. Our reinforced tissue matrix products have a limited shelf life and will expire if not timely used. Product development involves a high degree of risk, and there can be no assurance that our new product development efforts will result in any commercially successful products. ~~To~~ **46To** successfully market and sell our products in markets outside of the U. S., we must address many international business risks with which we have limited experience. Approximately **10 %,** 8 % ~~,~~ **and** 5 ~~% and 4~~ % of our revenue for the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , respectively, came from sales in markets outside of the U. S. Part of our sales strategy is to maintain our European presence. European sales are subject to a number of risks, including: ● difficulties in staffing and managing international operations; ● increased competition as a result of more products and procedures receiving regulatory approval in international markets; ● longer accounts receivable payment cycles and difficulties in collecting accounts receivable; ●

fluctuations in currency exchange rates; ● non- U. S. certification and regulatory clearance or approval requirements; ● difficulties in developing effective marketing campaigns in unfamiliar countries; ● customs clearance and shipping delays; ● complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; ● political, social, and economic instability abroad, terrorist attacks, and security concerns in general; ● the impact of the macroeconomic factors, including ~~COVID- 19 pandemic~~ **pandemics , epidemics and other public health outbreaks** , inflationary pressures and geopolitical conflicts ~~like~~ **, such as** the ~~war in~~ **ongoing Russia-** Ukraine **conflict and the current conflict in Israel and Gaza (including any escalation or expansion)** ; ● natural disasters and ~~global~~ pandemics ~~like COVID- 19~~ **, epidemics or public health outbreaks** , which result in lock- downs, travel restrictions and other restrictions on our ability to operate internationally; ● preference for locally produced products; ● potentially adverse tax consequences, including the complexities of non- U. S. value- added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings; ● the burdens of complying with a wide variety of non- U. S. laws and different legal standards; and ● increased financial accounting and reporting burdens and complexities. ~~46If~~ **If** one or more of these risks are realized, our business, financial condition and results of operations could be adversely affected. ~~Risks~~ **47Risks** Related to Our Reliance on Third PartiesWe are highly dependent upon Aroa, as the exclusive manufacturer and supplier of our OviTex ~~portfolio~~ **and OviTex PRS** products. In August 2012, we entered into our Aroa License which was amended and restated in July 2015. The Aroa License grants us an exclusive license in North America, the EU, United Kingdom, Norway, Switzerland, Russia and former Soviet satellite countries to certain intellectual property rights, including patents relating to the use of bovine and ovine rumen as a source of extracellular matrix. Under the Aroa License, Aroa is our exclusive manufacturer and supplier of our OviTex ~~portfolio products, consisting of OviTex, OviTex LPR~~ and OviTex PRS **products** . We are reliant upon the intellectual property we license from Aroa for the development and commercialization of our products. Under the Aroa License, we hold an exclusive license to certain intellectual and technology rights to develop, commercialize and sell certain endoform regenerative template products derived from cows and sheep. The Aroa License also provides for cooperative development of our products utilizing the licensed intellectual property and all of our products rely on intellectual property owned by Aroa and licensed to us under the Aroa License. The Aroa License imposes various developmental and regulatory requirements upon us along with requiring us to make milestone payments upon the achievement of certain commercial and regulatory milestones. If we fail to comply with our obligations under the Aroa License, Aroa will have the right to terminate the Aroa License, in which event we would not be able to develop and market our products. Aroa is required under the Aroa License to manufacture all of our OviTex ~~portfolio~~ **and OviTex PRS** products at its manufacturing and warehousing facility in Auckland, New Zealand. The production of all of our OviTex ~~portfolio~~ **and OviTex PRS** products in a single location exposes us to the risk of Aroa' s facility being harmed or rendered inoperable by natural or man- made disasters or pandemics, which may render it difficult or impossible for Aroa to perform its manufacturing and assembly activities for some time. Although we and Aroa intend to establish redundant production facilities to lessen the risk of production disruptions, we will need to ensure that any manufacturing facility complies with our quality expectations and applicable regulatory requirements. If we are unable to establish redundant manufacturing facilities in a timely manner, any disruption in the manufacture of our OviTex ~~portfolio~~ **and OviTex PRS** products at Aroa' s manufacturing and warehouse facility, the continued commercialization of our OviTex ~~portfolio~~ **and OviTex PRS** products, the supply of our OviTex ~~portfolio~~ **and OviTex PRS** products to customers and the development of any new reinforced tissue matrix products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations. Under the Aroa License, Aroa is responsible for supplying all of the raw materials and components used in the manufacture and assembly of our OviTex ~~portfolio~~ **and OviTex PRS** products. If Aroa is unable to supply the raw materials and components or to manufacture and assemble our OviTex ~~portfolio~~ **and OviTex PRS** products reliably and at the levels we anticipate or that are required by the market, we may be unable to acquire a substitute supply of raw materials and components on a timely basis, if at all. Under the Aroa License Aroa also holds the FDA clearances under which we commercialize our OviTex and OviTex LPR products, and maintains ultimate responsibility for all regulatory interactions with FDA relating to our OviTex ~~and~~ **producst, including** OviTex LPR ~~products~~ and decisions made with respect to changing or updating those clearances. If Aroa fails to comply with all applicable regulatory requirements and maintain the FDA clearances related to our OviTex ~~and OviTex LPR~~ products, we may be unable to commercialize our OviTex ~~and OviTex LPR~~ products on a timely basis, or at all. Our ability to supply our OviTex ~~portfolio~~ **and OviTex PRS** products commercially and to develop any future products depends, in part, on our ability to obtain these materials, components and products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. While Aroa has historically met our demand for its products and services on a timely basis in the past, we cannot guarantee that it will always be able to meet our demand for its products. If Aroa fails to meet demand or notifies us that it believes it will fail to meet demand for our OviTex ~~portfolio~~ **and OviTex PRS** products, we are required under the Aroa License to work with Aroa to cure its supply failure and may, only in certain circumstances and on a temporary basis, engage a replacement contract manufacturer to mitigate a failure by Aroa to meet demand for our OviTex ~~portfolio~~ **and OviTex PRS** products. As such, we are highly dependent upon Aroa' s continued ability to ~~47supply~~ -- **supply** our OviTex ~~portfolio~~ **and OviTex PRS** products at the levels we require and any production shortfall that impairs the supply of our **48OviTex and** OviTex ~~portfolio~~ **PRS** products could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for our OviTex ~~portfolio~~ **and OviTex PRS** products, which could adversely affect our product sales and operating results materially. We, or our partners, may experience development or manufacturing problems, capacity constraints, or delays in the production of our products that could limit the potential growth of our revenue or increase our losses. We may encounter unforeseen situations in Aroa' s manufacturing and assembly of our OviTex ~~portfolio~~ **and OviTex PRS** products that would result in delays or shortfalls in its production. For example, Aroa was unable to supply us with our products from September 2017 to December 2017 due to a quality testing

process failure identified by Aroa. Personnel shortages and reduced manufacturing capacity due to the COVID- 19 pandemic may also result in a disruption in production. Based upon our current planned market adoption we believe we will reach our capacity limitations in the Aroa facility. Aroa expanded its manufacturing capacity, with approximately 15, 000 square feet of additional manufacturing space being constructed in a neighboring facility, in 2022. If we are unable to successfully expand capacity, we may not be able to meet the demand for our products. In addition, Aroa' s production processes and assembly methods may have to change in order to accommodate any significant future expansion of its manufacturing capacity, which may increase our manufacturing costs, delay production of our products and adversely impact our business. Conversely, if demand for our OviTex ~~portfolio~~ **and OviTex PRS** products shifts such that Aroa' s manufacturing facility is operated below its capacity for an extended period, it may adjust its manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period. If Aroa' s manufacturing activities are adversely impacted or if it is otherwise unable to keep up with demand for our OviTex ~~portfolio~~ **and OviTex PRS** products by successfully manufacturing, assembling, testing and shipping our OviTex ~~portfolio~~ **and OviTex PRS** products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition and results of operations. Our products contain materials derived from animal sources and may become subject to additional regulation. Our products are manufactured using ovine rumen. Products that contain materials derived from animal sources are increasingly subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease, particularly progressive neurodegenerative disorders, from animals to humans via those materials. In addition, the COVID- 19 pandemic ~~has~~ heightened public awareness of animals and animal products as a disease vector. Products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for the transmission of infectious agents. Significant new regulation, or a ban of our products, could impair our current business or our ability to expand our business, and in the case of a ban or suspension, could have a material adverse effect on our business, financial condition and results of operations. Our supply of ovine rumen for use in manufacturing our products may be vulnerable to disruption due to natural disaster, disease or other events. The ovine rumen used in the manufacturing of our products is sourced through Aroa in New Zealand. Although Aroa obtains its supply of ovine rumen from jurisdictions with sheep that are not currently known to carry any prion disease (progressive neurodegenerative disorders, including scrapie disease), there can be no assurance that these flocks will remain prion disease- free or that a future outbreak or presence of other unintended and potentially hazardous agents would not adversely affect our products or patients that may receive them. The geographic concentration of our supply chain increases our vulnerability to disruption due to natural disasters, disease or other events. If there is a disruption in the supply of ovine rumen to our manufacturer and supplier, we may be unable to fulfill customer orders or delay the commercialization of new products. ~~48We~~ **49We** may also be prohibited from importing our products into the U. S. in the event of disease outbreak or other event impacting the sheep population in New Zealand. Any disruption in our supply lines could have a material adverse effect on our business, financial condition and results of operations. Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our products on a timely basis. Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point- to- point transport of our OviTex portfolio products (and would rely heavily on such providers for any other products we may commercialize and ship in the future) to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any of our products, it would be costly to replace such products in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our OviTex portfolio products (or any other products we commercialize in the future) and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, disease or other service interruptions affecting delivery services we use would adversely affect our ability to deliver our OviTex ~~portfolio~~ **and OviTex PRS** products (or any other products we commercialize in the future) on a timely basis. For example, disruptions to transportation infrastructure as a result of macroeconomic conditions ~~, including COVID- 19 pandemic,~~ may impact our ability to provide our products to our customers. Risks Related to Intellectual Property MattersWe may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. We may need to obtain licenses from third parties to advance our research or allow commercialization of our products, and we cannot provide any assurances that third- party patents do not exist which might be enforced against our products in the absence of such a license. The licensing and acquisition of third- party intellectual property rights is a competitive practice and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our products. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected products, which would have a material adverse effect on our business. If we fail to comply with our obligations under any license, collaboration or other agreements, we could lose intellectual property rights that

are necessary for developing and protecting our products. We have licensed certain intellectual property rights covering our current products from third parties, including Aroa. We are heavily dependent on our agreements with such third parties for our current products. If, for any reason, one or more of our agreements is terminated or we otherwise lose those rights, it could harm our business. Our license and other agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are ~~49covered~~ **50covered** by the licensed technology, having to negotiate new or reinstated licenses on less favorable terms, or enabling a competitor to gain access to the licensed technology. If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. Our commercial success will depend in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the U. S. and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. We own ~~fifteen~~ **seventeen** issued or allowed U. S. patents and have ~~nine~~ **sixteen** pending U. S. patent applications. As of December 31, ~~2022~~ **2023**, we had rights, whether through ownership or licensing, to ~~seventeen~~ **nineteen** issued or allowed U. S. patents, ~~nine~~ **sixteen** pending U. S. patent applications, ~~three~~ **five** issued non- U. S. patents and ~~four~~ **three** pending non- U. S. patent applications. Our issued U. S. patents will expire between 2035 and ~~2042~~ **2041**. The licensed patents will expire between 2029 and 2031. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We cannot provide any assurances that any of our patents, or patents to which we have ownership rights through licensing agreements, have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our OviTex ~~portfolio~~ **and OviTex PRS** products, any additional features we develop for our OviTex ~~portfolio~~ **and OviTex PRS** products or any new products we seek to develop in the future. Other parties may have developed technologies that may be related or competitive to our OviTex ~~portfolio~~ **and OviTex PRS** products, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal, scientific and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own, or to which we have ownership rights through licensing agreements, may not provide any protection against competitors. Furthermore, an adverse decision in a judicial or administrative proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products. Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the U. S. or abroad. Although an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could purchase our OviTex or OviTex PRS products and attempt to replicate the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around the relevant patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some non- U. S. ~~50countries~~ **51countries** do not protect our proprietary rights to the same extent as the laws of the U. S., and we may encounter significant problems in protecting our proprietary rights in these countries. In addition, proceedings to enforce or defend our patents, or patents to which we have ownership rights through licensing agreements, could put those patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of those patents are invalid or otherwise unenforceable. If any of the patents covering our OviTex ~~portfolio~~ **and OviTex PRS** products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. Third parties may assert ownership or commercial rights to inventions we develop. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using

certain intellectual property or may lose our exclusive rights in such intellectual property. Either outcome could harm our business and competitive position. Litigation or other proceedings or third- party claims of intellectual property infringement could require us to spend significant time and money, enter into license agreements for disputed intellectual property and could prevent us from selling our products. Our commercial success will depend in part on not infringing the patents or violating other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the U. S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. Patent applications in the U. S., the EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to develop and market our products. Third parties may assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as a strategy to impede our commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved, and the uncertainty of litigation may increase the risk of business resources and management' s attention being diverted to patent litigation. We have received, and we may in the future receive, letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Moreover, we may become party to adversarial proceedings regarding our or third- party patent portfolios. Such proceedings could include supplemental examination or contested post- grant proceedings such as review, reexamination, inter partes review, interference or derivation proceedings before the U. S. Patent and Trademark Office (" USPTO ") and challenges in U. S. District Courts. Patents may be subjected to opposition, post- grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be ~~51initiated~~ **52initiated** . Litigation and contested proceedings can also be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party. Any lawsuits resulting from such allegations could subject us to significant liability for damages and / or invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following: ● stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property; ● lose the opportunity to license our technology to others or to collect royalty payments; ● incur significant legal expenses, including, in some cases, the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; ● pay substantial damages (possibly treble damages) or royalties to the party whose intellectual property rights on which we may be found to be infringing; ● redesign products that contain the allegedly infringing intellectual property; and ● attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and / or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. In addition, we may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non- exclusive, which could give any competitors access to the same technology or intellectual property rights license to us. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a technically feasible way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain a required license, the holders of any such patents may be able to block us, our licenses or our collaborators from marketing products based on the disputed technology until such patents expire, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our products, services and technology. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. ~~52In~~ **53In** addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims

against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. We also rely upon copyright and trade secret protection, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome of any such claim is unpredictable. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed or reverse engineered by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our target markets and our business may be adversely affected. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity, possibly leading to market confusion and potentially requiring us to pursue legal action. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. If we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. We may be unable to enforce our intellectual property rights throughout the world. Filing, prosecuting and defending patents covering our products in all countries throughout the world would be prohibitively expensive, and the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U. S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Additionally, in the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and ~~53marketing~~ **54marketing** new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. Proceedings to enforce our patent or trademark rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We employ individuals who previously worked with other companies, including our competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal data, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Recent changes in U. S. patent laws may limit our ability to obtain, defend and / or enforce our patents. The U. S. has recently enacted and implemented wide ranging patent reform legislation. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the U. S. federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. Obtaining and maintaining our patent protection depends on compliance with various

procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and other patent agencies over the lifetime of the patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our products. ~~54Patent~~ **55Patent** terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. The term of any individual patent depends on applicable law in the country where the patent is granted. In the U. S., provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non- provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our products, when the terms of all patents covering a product expire, our business may become subject to competition from products identical or similar to ours. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may be unable to obtain a patent term extension in the U. S. under the Hatch- Waxman Act and in foreign countries under similar legislation. In the U. S., a patent that covers a drug product or medical device approved by the FDA may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our products, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: ● others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain; ● we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future; ● we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; ● we may not be able to successfully commercialize our products before our relevant patents we may have, or to which we have ownership rights through licensing agreements, expire; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ~~55~~ **56** ● it is possible that our current or future pending patent applications will not lead to issued patents; ● issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; ● our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● we may not develop additional proprietary technologies that are patentable; ● the patents of others may harm our business; and ● we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. Risks Related to Government RegulationOur products and operations are subject to extensive government regulation and oversight both in the U. S. and internationally. Our products are regulated as medical devices. We and our products are subject to extensive regulation in the U. S. and internationally including by the FDA and competent authorities of the EU member states. The FDA and other foreign equivalents regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post- market approval studies; and product import and export. The regulations to which we

are subject are complex, have become more stringent over time and are subject to further change. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; untitled letters; Form 483s; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties. We may not receive, or may be significantly delayed in receiving, the necessary clearances or approvals for our future products and modifications to our current products may require new 510 (k) clearances or PMA approvals, and may require us to cease marketing or recall the modified products until clearances or approvals are obtained. An element of our strategy is to continue to add new features and expand the indications and uses for our current products. In the U. S., before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive marketing authorization, such as either clearance under Section 510 (k) of the FDCA or approval of a PMA from the FDA, unless an exemption applies. Our products are cleared with the FDA, through clearances obtained and, with the exception of the clearances relating to our OviTex PRS products, held by Aroa, under Section 510 (k) of the FDCA, which permits marketing of a device if it is " substantially equivalent " to an already legally- marketed " predicate " device, which includes a device that has been previously cleared through the 510 (k) process, a device that was legally marketed prior to May 28, 1976 (preamendments device), a device that was originally on the U. S. market pursuant to an approved PMA and later downclassified, or a 510 (k)- exempt device. To be " substantially equivalent, " the proposed device must have the same intended use as the predicate device, ~~56and~~ **57and** either have the same technological characteristics as the predicate device or have different technological characteristics and the information in the premarket notification demonstrates that the device is as safe and effective and does not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. To date, our products have been the subject of cleared 510 (k) s, obtained and, with the exception of the clearances relating to our OviTex PRS products, held by Aroa. For more information regarding the regulation of our products, see " Business — Government Regulation. " Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510 (k) may require a new 510 (k) clearance. Both the PMA approval and the 510 (k) clearance process can be expensive, lengthy and uncertain. The FDA' s 510 (k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510 (k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. In the U. S., Aroa has obtained and holds 510 (k) clearances from the FDA to market our OviTex products and obtained the ~~501~~ **510** (k) clearances from the FDA held by us for our **first two** OviTex PRS products **, while we obtained and hold the 510 (k) clearance for our OviTex PRS Long- Term Resorbable product** . An element of our strategy is to continue to upgrade our reinforced tissue matrix products. We expect that any such modifications may require new 510 (k) clearances; however, future modifications may be subject to the substantially more costly, time- consuming and uncertain PMA process. The FDA will require a PMA, rather than a 510 (k) clearance for the use ~~if~~ **of** OviTex PRS in breast surgery. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: ● we may not be able to demonstrate to the FDA' s satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use; ● the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and ● the manufacturing process or facilities we use may not meet applicable requirements. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our future products under development. Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The failure to comply with applicable regulations could jeopardize our ability to sell our reinforced tissue matrix products and result in enforcement actions such as: ● warning letters, untitled letters or Form 483s; ● fines; ● injunctions; **58** ● civil penalties; ~~57~~ ● termination of distribution; ● recalls or seizures of products; ● delays in the introduction of products into the market; ● total or partial suspension of production; ● refusal to grant future clearances or approvals; ● withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and ● in the most serious cases, criminal penalties. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and results of operations. In addition, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study. Principal investigators for our clinical trials may serve as speakers or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and

may ultimately lead to the denial of marketing approval of one or more of our future products. To sell our products in member countries of the EEA our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation (Regulation 2017 / 745) (" MDR "), which was passed by the EU Parliament on April 5, 2017, and became effective on May 26, 2021. The MDR repeals and replaces the former Medical Devices Directive (Council Directive 93 / 42 / EEC) and the Active Implantable Medical Devices Directive (Council Directive 90 / 385 / EEC). Compliance with the new MDR requirements is a prerequisite to be able to affix the Conformité Européenne, or CE, mark to our products, without which they cannot be sold or marketed in the EEA. In the EEA, we have obtained the CE mark for our OviTex products. For more information regarding regulation of our products, see " Business — Government Regulation. " An element of our strategy is to continue to add new features and expand the indications and uses for our current products. Any modification to a 510 (k)- cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510 (k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer' s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. Such modifications can be expensive and uncertain in time and outcome. We may not be able to obtain additional 510 (k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified until we obtain clearance or approval, which could harm our operating results and require us to ~~redesign~~ **59redesign** such products. In these circumstances, we may be subject to significant enforcement actions, including significant fines or penalties. ~~58International~~ -- **International** regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non- U. S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non- U. S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition and results of operations. Although we have obtained regulatory clearance for our products, they will remain subject to extensive regulatory scrutiny. We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacturing, marketing, advertising, medical device reporting, selling and promoting our products. For example, we must submit periodic reports to the FDA as a condition of our clearance under Section 510 (k). These reports include safety and effectiveness information about the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Even after we have obtained the proper regulatory approval to market our products, they will be subject to ongoing regulatory requirements for design, development, manufacturing, testing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, recalls and field safety corrective actions, conduct of post- marketing studies and submission of safety, effectiveness and other post- market information, including both federal and state requirements in the U. S. and requirements of comparable non- U. S. regulatory authorities. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA and applicable state regulatory authorities, which may include any of the following sanctions: ● issue warning or untitled letters that would result in adverse publicity or may require corrective advertising; ● fines, injunctions, consent decrees and civil penalties; ● recalls, termination of distribution, administrative detention, or seizure of our products; ● customer notifications or repair, replacement or refunds; ● operating restrictions or partial suspension or total shutdown of production; ● delays in or refusal to grant our requests for future clearances under Section 510 (k) or premarket approvals or EU regulatory approvals of new products, new intended uses, or modifications to existing products; ● withdrawal or suspension of regulatory clearances or approvals; ● FDA refusal to issue certificates to non- U. S. governments needed to export products for sale in other countries; and ● criminal prosecution. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory ~~sanctions~~ **60sanctions** are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations. ~~59Our~~ -- **Our** products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our products or terminate production if we fail to comply with these regulations. The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA' s QSR which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, Aroa must maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various EU laws and regulations governing manufacturing. Aroa may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. For example, following an inspection in March 2017, Aroa received an FDA Form 483 that contained multiple observations related to its manufacturing processes and procedures. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things:

untitled letters or warning letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA' s refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees. Any of these actions could significantly and negatively affect **the** supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs. If guidelines for soft- tissue reconstruction surgery change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for our OviTex and OviTex PRS products or other products we may commercialize in the future. If guidelines for soft- tissue reconstruction surgery change or the standard of care for reconstructing tissue evolves, we may need to redesign the applicable product and seek new approvals from the FDA. Our clearances under Section 510 (k) of the FDCA are based on current soft- tissue reconstruction surgery guidelines. If the guidelines change so that different surgeries or products become desirable, the clinical utility of one or more of our OviTex ~~portfolio~~ **and OviTex PRS** products or other products we may commercialize in the future could be diminished and our business could be adversely affected. If any of our products cause or contribute to a death, serious injury, or other adverse medical events, or malfunction in certain ways, we will be required to report these events to FDA and other comparable regulatory authorities under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. If we fail to comply with our reporting obligations, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. We are subject to the FDA' s medical device reporting regulations and similar EU and other foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse ~~event~~ **61event** that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including untitled letters, warning letters, administrative actions, criminal ~~60prosecution~~ -- **prosecution** , imposition of civil monetary penalties, revocation of related approvals, seizure of our products or delay in clearance or approval of future products. The FDA and foreign regulatory agencies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. For example, in April 2018, Aroa, as the product manufacturer, issued a voluntary recall of our resorbable OviTex products due to a reduction in the labeled shelf life of such products from 24 months to 18 months. The recall included a total of 1, 974 units from 48 manufacturing lots and was ultimately terminated in April 2019. A government- mandated or voluntary recall by us could also occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices, or the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our future products under development. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance of or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict

the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. ~~61On~~ **62On** April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017 / 745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i. e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The Medical Devices Regulation is intended to, among other things, establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The MDR became fully effective on May 26, 2021. It includes new regulations which, among other things: ● strengthen the rules on placing devices on the market and reinforce surveillance once they are available; ● establish explicit provisions on manufacturers' responsibilities for the follow- up of the quality, performance and safety of devices placed on the market; ● improve the traceability of medical devices throughout the supply chain to the end- user or patient through a unique identification number; ● establish a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and ● strengthen rules for the assessment of certain high- risk devices, which may have to undergo an additional check by experts before they are placed on the market. Failure to comply with these regulations may harm our business. Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new devices to be reviewed and / or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Our relationships with surgeons, patients and payors in the U. S. are subject to applicable anti- kickback, fraud and abuse laws and regulations. Our current and future operations with respect to the commercialization of our products are subject to various U. S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third- party ~~62payors~~ -- **payors**, surgeons and other healthcare professionals. **For more information, see** ~~The laws are described in greater detail in~~ the ~~section~~ **sections entitled** ~~below under~~ " Business ~~—~~ **–** ~~Government~~ **63Government** Regulation **–** ~~," and include, but are not limited to: ● the U. S. federal~~ Anti- Kickback ~~Statute~~ **Statutes**, **–** ~~which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● the U. S. federal false claims laws, including the civil~~ False Claims ~~Act (which can be enforced through " qui tam,~~ **Laws; – Transparency Laws; and – Other Federal Healthcare Fraud and Abuse Laws** " **in** ~~or whistleblower actions, by private citizens on behalf of the federal government), which prohibits any person from, among other things~~ -- **this Annual**, ~~knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U. S. federal government; ● the U. S. federal Health Insurance Portability and Accountability Act of 1996 which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately- funded benefits programs; similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report~~ **Report** ~~annually to the Centers for Medicare and Medicare Services, or CMS, information related to certain payments made in the preceding calendar year and other transfers of value to physicians, certain other licensed healthcare practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and ● state laws and regulations, including state anti- kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require medical device companies to comply with the medical device industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict~~

~~payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug and device manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities~~ . The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or medical device company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. Certain physicians who influence the ordering or use of our products in procedures they perform have ownership interests in us and / or receive compensation for consulting services provided to us. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. ~~63To~~ **To** enforce compliance with healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may also have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlements could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. We are subject to anti- bribery, anti- corruption, and anti- money laundering laws, including the U. S. Foreign Corrupt Practices Act, in which violations of these laws could result in substantial penalties and prosecution. We are exposed to trade and economic sanctions and other restrictions imposed by the U. S. and other governments and organizations. The U. S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U. S. Foreign Corrupt Practices Act, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control. In addition, the U. K. Bribery Act of 2010 (" Bribery Act "), prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that " fails to prevent bribery " by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented " adequate procedures " to prevent bribery. Under these laws and regulations, as well as other anti- corruption laws, anti- money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. We face risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices. Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable ~~laws~~ **64laws** and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to users' accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain users' personal data or prevent use of their accounts. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U. S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, ~~64some~~ -- **some** of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the CCPA on June 28, 2018, which took effect on January 1, 2020. The CCPA created individual privacy rights for California consumers and increased the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches in certain instances that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Additionally, ~~a new privacy law,~~ the California Privacy Rights Act, or the CPRA, ~~was approved by California voters in the election of November 3, 2020. The CPRA, which~~ took effect in most material respects on January 1, 2023 ~~,~~ **. The CPRA** modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses to comply. A failure to comply with these current or future federal and state laws and regulations and industry standards relating to data privacy and security

could lead to investigatory or regulatory action, private litigation or class actions that could result in exposure to civil or criminal penalties, monetary or statutory damages, attorney fee awards and / or exposure to adverse publicity that could negatively affect our operating results and business. This risk is enhanced in certain jurisdictions as we expand our operations internationally. The EU' s GDPR became effective in May 2018. The GDPR applies extraterritorially and imposes several stringent requirements for controllers and processors of personal data, of data subjects residing in the European Economic Area. For example, the GDPR imposes higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of personal data and pseudonymised (i. e., key-coded) data and additional obligations when we contract third- party processors in connection with the processing of the personal data. This risk is increased because EU member states have made their own laws and regulations limiting the processing of personal data, including special categories of data (e. g., racial or ethnic origin, political opinions, religious or philosophical beliefs) and profiling and automated individual decision- making of individuals, which limits our ability to process personal data or other data and could cause our compliance costs and liability risks to increase, harming our business and financial condition. Further, the United Kingdom' s exit from the European Union, referred to as Brexit, has created uncertainty regarding data protection regulation in the United Kingdom. The United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR that took effect in January 2021 (UK GDPR). Currently, the EU GDPR and UK GDPR remain largely aligned, but the UK has announced plans to reform the country' s data protection legal framework in its Data Reform Bill, which will introduce significant changes from the EU GDPR. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EEA and the UK, and we will need to amend our processes and procedures to align with the new framework. Non- compliance with GDPR, and UK GDPR, is subject to significant penalties, including fines of up to € 20. 0 million (£ 17. 5 million under UK GDPR) or 4 % of total worldwide revenue, whichever is greater. The implementation and enforcement of the GDPR (and UK GDPR) may subject us to enforcement risk and requirements to change certain of our data collection, processing and other policies and practices. We could incur significant costs investigating and defending such claims and, if we are found liable, significant damages. If any of these events were to occur, our business and financial results could be adversely affected. Other jurisdictions outside the EU and the United ~~Kingdom~~ **65Kingdom** are similarly introducing or enhancing laws and regulations relating to privacy and data security, which enhances risks relating to compliance with such laws. The GDPR also regulates cross- border transfers of personal data and requires transferee countries to have protections equivalent to protections available in the EU. The GDPR imposes strict rules on the transfer of personal data to countries outside the EEA, Switzerland or the United Kingdom, including the United States, to other countries in respect of which the European Commission or the United Kingdom government has not issued a so- called " adequacy decision " or " adequacy regulation " (known as " third countries "), unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. This includes putting in place the European Commission' s Standard Contractual Clauses (SCCs) for transfers outside of the EEA and a similar transfer mechanism for transfers of personal data outside of the United Kingdom, the International Data Transfer Agreement or Addendum (IDTA). Under both the GDPR and the UK GDPR, exporters are also required to assess the risk of the data transfer on a case- by- case basis, ~~65including~~ -- **including** conducting an analysis of the laws in the destination country. The SCCs had to be in place by December 27, 2022, whereas the IDTA ~~must~~ **had to** be implemented in all existing contracts by March 21, 2024. Finalizing the implementation of the updated SCCs and UK IDTA, and conducting the required risk assessments, may continue to necessitate significant contractual overhaul of our data transfer arrangements with customers, sub- processors and vendors. On June 28, 2021, the European Commission published its decision recognizing the United Kingdom as having adequate laws to the protect the rights and freedoms of data subjects such that personal data may transfer to from the EU to the United Kingdom without an approved transfer mechanism. The decision is effective for four years and its continuing effect is dependent on United Kingdom and regulation on data privacy not diverging materially from the GDPR. The United Kingdom Government also confirmed that data transfers to the EU remain free flowing. Compliance with U. S. federal and state laws and foreign 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. Failure to comply with United States and foreign data protection laws and regulations could result in 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. And 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. The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to successfully commercialize our products and affect the prices we may obtain. **Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For more information, see the section entitled " Business – Government Regulation – U. S. Healthcare Reform " in this Annual Report.** In the U. S. **, for example** , the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the healthcare industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device

manufacturers, and impose additional health policy reforms. ~~There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $ 1. 2 trillion for the fiscal years 2012 through 2021, triggering the legislation' s automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2. 0 % per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2 % reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was designed to provide financial support and resources to individuals and businesses affected by the COVID- 19 pandemic, suspended the 2 % Medicare sequester from May 1, 2020 to December 31, 2021, later extended through March 31, 2022. Following the suspension, a 1 % payment reduction began April 1, 2022, and remained through June 30, 2022. The 2 % payment reduction resumed on July 1, 2022. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U. S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. On December 18, 2019, the Fifth Circuit U. S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire 66Affordable Care Act. An appeal was taken to the U. S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. Further changes to and under the Affordable Care Act remain possible, but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future.~~ At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control healthcare costs, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. ~~We~~ **66We** expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved. Our business involves the use of hazardous materials and we and Aroa must comply with environmental laws and regulations, which may be expensive and restrict how we do business. Aroa' s activities in manufacturing our products may involve the controlled storage, use and disposal of hazardous materials. Aroa is or may be subject to federal, state, local and non- U. S. laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe that Aroa' s safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, federal, state or other applicable authorities may curtail Aroa' s use of these materials and interrupt their business operations which could adversely affect our business. Compliance with environmental laws and regulations may be expensive and non- compliance could result in substantial liabilities, fines and penalties, personal injury and third- party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and results of operations. Risks Related to Our Business and ProductsOur financial results may fluctuate significantly and may not fully reflect the underlying performance of our business. Our quarterly and annual results of operations may vary significantly in the future, and period- to- period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control. ~~67Factors~~ -- **Factors** that may cause fluctuations in our quarterly and annual results include: ● surgeon and patient adoption of our products; ● timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; ● changes in coverage policies by third- party payors that affect the reimbursement of procedures in which our products are used; ● unanticipated pricing pressure; ● our ability to obtain and maintain regulatory clearance or approval for any products in development or for our current products for additional indications or in additional jurisdictions; **67** ● the hiring, retention and continued productivity of our sales representatives; ● our ability to expand the geographic reach of our sales and marketing efforts; ● results of clinical research and trials on our existing products and products in development; ● delays in, or failure of, component and raw material deliveries by Aroa; ● recalls or other field

safety corrective actions by Aroa; ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters such as earthquakes, floods or public health emergencies such as the COVID- 19 pandemic; and ● positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry. Because our quarterly and annual results may fluctuate, period- to- period comparisons may not be the best indication of the underlying results of our business. ~~In particular, we cannot predict at this time the extent of the impact that the COVID- 19 pandemic will have on our sales and financial results.~~ These fluctuations may also increase the likelihood that we will not meet our forecasted performance, which could negatively affect the market price for our common stock. We may be unable to compete successfully with larger competitors in our highly competitive industry. The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our products. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our products, which would have a material adverse effect on our business, financial condition and results of operations. In the U. S., we currently compete with LifeCell Corporation, a subsidiary of AbbVie, ~~and~~ Davol Inc., a subsidiary of Becton, Dickinson and Company **, MTF Biologics and RTI Surgical** , which produce, among other things, soft- tissue reconstruction surgery products, including Strattice and **Alloderm,** Phasix **, FlexHD and Cortiva** , respectively. In the EEA, we compete with Bard, a subsidiary of Becton, Dickinson and Company, who produces other soft- tissue reinforcement products. Many of these competitors are large, well- capitalized companies with significantly greater market share and resources than us, selling products that have been on the market prior to the commercialization of our products. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can, while benefiting from greater brand awareness. We believe other emerging businesses are in the early stages of developing similar products designed for soft- tissue reconstruction ~~68surgery~~ -- **surgery** . Although we are the only ovine- derived implantable product designed for soft- tissue reconstruction surgery, there are other soft tissue reconstruction surgery products derived solely, or in part, from other biological sources. Most of the other soft- tissue reconstruction surgery products currently have a greater penetration into the soft tissue reconstruction surgery market. Often, other soft- tissue reconstruction surgery products with which our products compete are marketed as part of a bundled product line, which may provide our potential customers a better price- per- product than we could offer. If we are unable to penetrate the soft- tissue reconstruction surgery market or offer competitive pricing on our products compared with products sold as part of a bundled product line, it could have a material adverse effect on our business, financial condition and results of operations. In addition, competitors with greater financial resources could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenue to decline and would harm our business. ~~We~~ **68We** may be unable to renew existing contracts with GPOs or obtain additional contract positions with major GPOs and ~~integrated delivery networks, or~~ IDNs, for our products, and even if we are able to do so, such contracts may not generate sufficient sales of our products. Many existing and potential customers for our products within the U. S. are members of GPOs and IDNs, including accountable care organizations or public- based purchasing organizations, and our business strategy is focused on entering into major contracts with these organizations. Our products can be contracted under national tenders or with larger hospital GPOs. GPOs and IDNs typically award contracts on a category- by- category basis through a competitive bidding process. We are currently responding to bids and negotiating a number of GPO and IDN agreements. We may not be able to renew existing contracts with GPOs or IDNs and due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the U. S., we may not be able to obtain additional contract positions with major GPOs and IDNs for our products. If we are unable to renew existing contracts with GPOs or IDNs, our net sales and results of operations may be materially and adversely affected. In addition, while having a contract with a major purchaser for a given product category can facilitate sales, sales volumes of those products may not be maintained. For example, GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category. Even if we are the sole contracted supplier of a GPO or IDN for our product category, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days' notice. Supply chain disruptions could adversely impact our operations and financial condition. Global supply chains have been ~~disrupted~~ **impacted** because of the **lingering economic impacts** COVID- 19 pandemic **, recent geopolitical tensions such as the ongoing Russia- Ukraine conflict and the current conflict in Israel and Gaza (including any escalation or expansion)** and other factors, and this may impact the availability of raw materials and components used in the manufacture of our products. Additionally, even when we and our suppliers are able to source such materials and components, they may cost more and may only be available on a delayed basis. Higher materials and component costs could adversely affect our margins if we are unable to pass such costs along to customers in the form of price increases. Delays in receipt of materials and components could also interrupt our production and cause us to go into backorder on certain of our products, further exacerbating the effect of the global supply chain disruption. We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a product is cleared or approved for commercial sale by the FDA, and manufactured in facilities licensed and regulated by the FDA. Any side effects, manufacturing defects or misuse associated with our products could result in patient injury or death. The industry in which we operate has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our products cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of Aroa may be the basis for a claim ~~69against~~ -- **against** us. Product liability claims may be brought against us by patients, healthcare

providers or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in substantial litigation costs, product recalls or market withdrawals, decreased sales and demand for our products and damage to our reputation. While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by ~~patients~~ **69patients** as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations. Although we have product liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. In addition, our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. The continuing development of our products depends upon our maintaining strong working relationships with surgeons. The research, development, marketing and sale of our current and future products and any future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with surgeons. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Surgeons assist us in clinical trials and in marketing, and as researchers, product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations. At the same time, the medical device industry' s relationship with surgeons is under increasing scrutiny by the U. S. Department of Health and Human Services Office of Inspector General (" OIG "), the U. S. Department of Justice (" DOJ "), the state attorneys general and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry' s relationships with surgeons or an investigation into our compliance by the OIG, the DOJ, state attorneys general and other government agencies, could have a material adverse effect on our business, financial condition and results of operations. Additional information regarding the laws impacting our relationships with surgeons and other healthcare professionals can be found above under " Risks Related to Government Regulation. " We have limited data and experience regarding the safety and efficacy of certain of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products. Our single arm multicenter post- market clinical study, which we refer to as our BRAVO study, was fully enrolled at 92 patients. We conducted this study to support the marketing of our OviTex products for their cleared indicated uses, and do not currently have any clinical data for use of our OviTex PRS products in patients. The long- term effects of using certain of our products in a large number of patients have not been studied and the results of short- term clinical use of such products do not necessarily predict long- term clinical benefits or reveal long- term adverse effects. The results of preclinical studies and clinical studies of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate ~~70results~~ -- **results** in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim or preliminary data from our clinical studies, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim results that we report may differ from future results of the same trials, ~~or~~ **70or** different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim or preliminary data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views,

activities or otherwise regarding a particular drug, product candidate or our business. If the interim or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to use such results to support the marketing of our products may be jeopardized. The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate. Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third- party estimates, including, without limitation, the number of hernia and soft- tissue reconstruction surgery patients and overall market and the assumed prices at which we can sell our products. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our products may prove to be incorrect. If the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory. Our reinforced tissue matrix products have a limited shelf life and will expire if not timely used. To ensure adequate inventory supply, we must forecast inventory needs and place orders with Aroa based on our estimates of future demand for our reinforced tissue matrix products. Our ability to accurately forecast demand for such products could be negatively affected by many factors, including: ● product introductions by competitors; ~~71~~ ● an increase or decrease in surgeon demand for our products or for products of our competitors; ● our failure to accurately manage our expansion strategy; ● our failure to accurately forecast surgeon acceptance of new products; ● our failure to obtain contracts with a significant number of GPOs and IDNs; ● unanticipated changes in general market conditions or regulatory matters; ● the severity and duration of market disruptions as a result of the COVID- 19 outbreak; ~~and~~ **and71** ● weakening of economic conditions or consumer confidence. Inventory levels in excess of customer demand may result in inventory write- downs or write- offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Additionally, we are subject to the risk that a portion of our inventory will expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Conversely, if we underestimate customer demand for our products, Aroa may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or Aroa may not be able to allocate sufficient capacity to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our products and our results of operations. We rely on our own direct sales force for our products, which may result in higher fixed costs than our competitors and may slow our ability to reduce costs. We rely on our own direct sales force, which as of December 31, ~~2022~~ **2023** consisted of ~~61~~ **94** representatives in the U. S. and ~~7~~ **10** representatives in Europe, to market and sell our products. A direct sales force may subject us to higher fixed costs than those of companies that market competing products through independent third parties, due to the costs that we will bear associated with employee benefits, training and managing sales personnel. As a result, we may be at a competitive disadvantage. Additionally, these fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products, which could have a material adverse effect on our business, financial condition and results of operations. Our employees, independent contractors, consultants, commercial partners, distributors and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the rules of the FDA and other similar foreign regulatory bodies; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the U. S. and similar foreign fraudulent misconduct laws; (iv) data privacy laws and other similar non- U. S. laws; or (v) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines ~~72or~~ **or** other sanctions, including the imposition of civil, criminal and administrative penalties, additional integrity reporting and oversight obligations and possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations. We could be adversely affected by any interruption to our ability to conduct business at our current location. We do not have redundant facilities. We perform substantially all of our research and development and back- office activity and maintain all our finished goods inventory in a single location in Malvern, Pennsylvania. Our facility, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, ~~flooding~~ **72flooding** , fire, public health emergencies such as pandemics and power outages, which may render it difficult or impossible for us to perform our customer service research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it

may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all. If we **or our vendors** experience **a cybersecurity incident,** significant disruption or a breach ~~in~~ **of** our information technology systems, our business could be adversely affected. We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing products, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal and tax requirements, data security and other processes necessary to manage our business. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information, ~~and~~ changing customer patterns **and an evolving threat landscape** . If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security **incidents** ~~breaches, and our business continuity plans do not effectively compensate on a timely basis~~ , we may experience interruptions in our operations **or security breaches** , which could have an adverse effect on our business. If we fail to maintain or protect our information systems and data integrity effectively, we could lose existing customers, have difficulty attracting new customers, suffer backlash from negative public relations, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or suffer other adverse consequences. Furthermore, any breach in our information technology systems could lead to the unauthorized access, disclosure and use of non- public information from our patient registry or other patient 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 and damage to our reputation. **Although we develop and maintain systems and controls designed to prevent these events from occurring, there can be no assurance that our internal information technology systems or those of our third- party vendors will be sufficient to protect against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security incident, industrial espionage attacks, ransomware, or insider threat attacks. If a material security incident related to our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our cybersecurity measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks, including costs to deploy additional personnel and protection technologies, train employees, engage third- party experts and consultants, and identify replacement vendors if necessary, which could materially and adversely affect our business, financial condition and results of operations. In addition, we could be subject to regulatory actions and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices.** If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations. As of December 31, ~~2022~~ **2023** , we had federal and state net operating loss carry forwards (" NOLs ") of approximately $ ~~212~~ **239** . ~~3~~ **4** million and $ ~~173~~ **196** . ~~5~~ **1** million, respectively. The federal carry forwards for losses incurred prior to 2018 will begin expiring in 2032 for federal purposes. Federal net operating losses incurred in 2018 and onward have an indefinite expiration under the 2017 Tax Cut & Jobs Act. The state carry forwards will begin expiring in ~~2026~~ **2027** . A full allowance for the value of the NOLs is provided for in our audited financial statements for the year of December 31, ~~2022~~ **2023** included in this ~~Annual~~ **73Annual** Report on Form 10- K. We cannot guarantee what the ultimate outcome or amount of the benefit we may receive from the NOLs, if any, will be. If we become profitable in the future, our ability to use net operating loss carryforwards and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations. ~~73Risks~~ -- **Risks** Related to Our SecuritiesThe trading price of the shares of our common stock has been and could in the future be highly volatile. The price of our common stock has been and may continue to be volatile. Even though our common stock is listed on the Nasdaq Global Market (" Nasdaq "), an active trading market for our common stock may not be sustained. The lack of an active trading market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive trading market may also impair our ability to raise capital by selling shares of our common stock and enter into strategic partnerships or acquire other complementary products, technologies or businesses by using shares of our common stock as consideration. Furthermore, there can be no guarantee that we will continue to satisfy the continued listing standards of Nasdaq. If we fail to satisfy the continued listing standards, we could be de- listed, which would have a negative effect on the price of our common stock. We cannot predict the prices at which our shares of common stock may trade. The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including: ● the volume and timing of sales of our products; ● the introduction of new products or product enhancements by us or others in our industry; ● disputes or other developments with respect to our or others' intellectual property rights; ● our ability to develop, obtain regulatory clearance for, and market new and enhanced products on a timely basis; ● product liability claims or other litigation; ● quarterly variations in our results of operations or those of others in our industry; ● media exposure of our products or of those of others in our industry; ● changes in governmental regulations or in reimbursement; ● changes in earnings estimates or recommendations by securities analysts; ● broad trends impacting companies within the pharmaceutical, biotechnology and medical technology industries; and ● general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors, including any economic downturn as a result of the COVID- 19 pandemic, or macroeconomic factors such as geopolitical tensions or the outbreak **or escalation** of hostilities or war. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating

performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance ~~. Further, on March 10, 2023, the FDIC took control and was appointed receiver of SVB. The financing uncertainty pharmaceutical, biotechnology and medical technology companies may now face as a result of SVB' s entry into receivership may cause significant volatility with respect to pharmaceutical, biotechnology, and medical technology company stocks, which in turn could negatively impact the trading price of our common stock~~ . In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock 74price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management' s attention and resources from our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the agreement governing our credit facility precludes, and any future debt agreements may preclude us from paying cash dividends. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any. Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders. Our officers, directors and principal stockholders each holding more than 5 % of our common stock, collectively, control approximately ~~56~~ **46** % of our outstanding common stock. As a result, these stockholders, if they act together, will be able to significantly influence our management and affairs and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our capital stock or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders. We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not " emerging growth companies. " In particular, while we are an " emerging growth company " (i) we will not be required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act, (ii) we will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor' s report on financial statements, (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. We may remain an emerging growth company until as late as December 31, 2024, the fiscal year- end following the fifth anniversary of the completion of our IPO, though we may cease to be an " emerging growth company " earlier under certain circumstances, including if (i) we have more than $ 1. 235 billion in annual revenue in any fiscal year, (ii) the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of any June 30 or (iii) we issue more than $ 1. 0 billion of non- convertible debt over a three- year period. The exact implications of the JOBS Act are still subject to interpretations and guidance by the SEC and other regulatory agencies, and we cannot assure you that we will be able to take advantage of all of the benefits of the JOBS Act. In addition, investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile. 75We are at risk of securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, the price of our stock could decline. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price to decline. Provisions in our corporate charter documents and under Delaware law could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our fourth amended and restated certificate of incorporation and our ~~second~~ **third** amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. As our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions provide, among other things, that: ● our board of directors has the exclusive right to expand the size of our board of

directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; ● our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three- year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; ● our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; ● a special meeting of stockholders may be called only by the chair of our board of directors, our chief executive officer (or president, in the absence of a chief executive officer) or a majority of our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; ● our fourth amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; ● our board of directors may alter certain provisions of our ~~second~~ **third** amended and restated bylaws without obtaining stockholder approval; 76 ● the approval of the holders of at least two- thirds of our shares entitled to vote at an election of our board of directors is required to adopt, amend or repeal our ~~second~~ **third** amended and restated bylaws or repeal the provisions of our fourth amended and restated certificate of incorporation regarding the election and removal of directors; ● stockholders must provide advance notice and additional disclosures to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain voting control of our shares; and ● our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (" DGCL ") which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our fourth amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our fourth amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the United State District Court for the District of Delaware) is the exclusive forum, to the fullest extent permitted by law, for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our fourth amended and restated certificate of incorporation or ~~second~~ **third** amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, except, in each case, (A) any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than such court, or (C) for which such court does not have subject matter jurisdiction, in all cases subject to the courts having jurisdiction over indispensable parties named as defendants. This provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigations costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our fourth amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. Alternatively, if a court were to find the choice of forum provision contained in our fourth amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. This provision will not apply to actions arising under the Securities Act or Exchange Act. Our fourth amended and restated certificate of incorporation and ~~second~~ **third** amended and restated bylaws further provide that the federal district courts of the U. S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Section 22 of the Securities Act, however, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is **uncertainty as to whether a** 77