

Risk Factors Comparison 2025-02-28 to 2024-03-04 Form: 10-K

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Investing in our common shares involves a high degree of risk. We operate in a rapidly changing economic and competitive environment that presents numerous risks, many of which are driven by factors that we cannot control or predict. The following risk factors describe circumstances or events that could have a negative effect on our business, financial condition or operating results. You should consider the following risks carefully, together with all the other information in this Annual Report on Form 10-K, including our consolidated financial statements and notes thereto, before you invest in our common shares. If any of the following risks occur, our business, financial condition, or operating results, could be adversely affected. As a result, the trading price of our common shares could decline, and you could lose part or all of your investment. Additional risks and uncertainties not currently known to us or that we currently believe are not material could also impair our business, financial condition or operating results.

Risks Related to the Development and Commercialization of Our Products We have a limited operating history in the United States and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets. Our **products were marketed solely in countries outside of the United States from October 2010 until 510 (k) clearance for the Motiva Flora SmoothSilk Tissue Expander in October 2023 and FDA approval of our** Motiva Implants ~~have been marketed solely in~~ **September 2024** ~~countries outside of the United States since October 2010,~~ and as such, we have a limited operating history **in the United States** upon which to evaluate our business and forecast our future net sales and operating results. ~~In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive markets, particularly companies that develop and sell medical devices. These risks include our ability to:~~ • **implement and execute our business strategy;** • **expand and improve the productivity of our direct sales force, distributors and marketing programs to grow sales of our products;** • **increase awareness of our brands and build loyalty among plastic surgeons and patients;** • **manage expanding operations;** • **respond effectively to competitive pressures and developments;** • **enhance our existing products and develop new products;** • **maintain and obtain regulatory clearance or approval of our existing products and commercialize new products;** • **respond to changing regulations associated with medical devices across all geographies;** • **perform clinical trials with respect to our existing products and any new products;** • **attract, retain and motivate qualified personnel in various areas of our business;** and • **obtain and maintain coverage and adequate levels of reimbursement for our products.** ~~Due to our limited operating history in the United States, we may not have the institutional knowledge or experience to be able to~~ **implement and execute our business strategy** ~~and~~ **effectively address these -- the and other** risks that we may face. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of ~~these~~ **this** or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer. Our success depends, in part, on our ability to continue to enhance our existing products and services and develop or commercialize new products and services that respond to customer needs and preferences, which we expect will require us to incur significant expenses. In recent years, we have incurred significant costs in connection with the **research and** development of Motiva Implants, the Mia Femtech technology, and **our other product candidates,** products and services. ~~We expect our research and development expenses to increase significantly as we continue with our IDE clinical trial in the United States. We have been incurring significant expenses to expand our sales and marketing organization to support sales of Motiva Implants, including but not limited to a direct sales force in Brazil and several European countries, as well as in preparation of the future commercialization in the United States if we receive FDA approval. We may not be able to compete effectively with our competitors, and ultimately satisfy the needs and preferences of our customers, unless we can continue to enhance existing products and develop or acquire new innovative products and services. Product development requires the investment of significant financial, technological and other resources. Product improvements and new product introductions also require significant planning, design, development and testing at the product and manufacturing process levels. We may not be able to timely or effectively develop product improvements or new products and services. Likewise, we may not be able to acquire new products on terms that are acceptable to us, or at all. Furthermore, in most countries, we need to obtain regulatory approval in order to market and sell our products, which may limit our ability to act quickly in scaling commercialization in those countries, including the United States. Our competitors' new products may beat our products to market, be more effective or safer or have new features, obtain better market acceptance or render our products and services obsolete. Any new or modified products and services that we develop may not receive regulatory clearance or approval, or achieve market acceptance or otherwise generate any meaningful sales or profits for us. The clinical trial process is lengthy and..... results of operations and growth prospects.~~ Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages ~~or global health concerns~~ could ~~hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise~~ prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. 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, the ability to hire and retain key personnel, the ability to accept the payment of user fees, statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. ~~Average~~ **The new Trump Administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing**

statutes through rulemaking, issuance of guidance, and review and approval of applications times at the agency have fluctuated in recent years as a result. Further in addition, government funding of the SEC, FDA, and other government agencies on which our operations may rely, including those 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 drugs and devices to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, during various times in the recent past, the U. S. government has shut down and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of foreign manufacturing facilities and routine surveillance inspections of domestic manufacturing facilities in 2020. If a prolonged government shutdown occurs, or if other events, including global health concerns, uncertainty regarding the FDA's funding, operations or policy goals, prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities in a timely manner, 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. Further, in our operations as a public company, future federal government shutdowns or delays in annual appropriations or budget freezes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Any future distribution or commercialization agreements we may enter into with respect to our current or planned products may place the development of these products outside our control, or may otherwise be on terms unfavorable to us. We may enter into additional distribution or commercialization agreements with third parties with respect to our current or planned products, for commercialization in or outside the United States. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid- size medical device and diagnostic companies, regional and national medical device and diagnostic companies, and distribution or group purchasing organizations. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our planned products. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable planned products. Collaborators may own or co- own intellectual property covering our products that results from our collaboration with them. In such cases, we would not have the exclusive right to commercialize such intellectual property. Any termination or disruption of collaborations could result in delays in the development of planned products, increases in our costs to develop the planned products or the termination of development of a planned product. If we are unable to educate clinicians on the safe, effective and appropriate use of our products and designed surgeries, we may experience unsatisfactory patient outcomes, negative publicity and increased claims of product liability and may be unable to achieve our expected growth. We make extensive physician medical education resources available to clinicians in an effort to ensure that they have access to current treatment methodologies, are aware of the advantages and risks of our Motiva Implants and other products and are educated regarding the safe and appropriate use of our products. It is critical to the success of our business to broadly educate clinicians who use or desire to use our products to provide them with adequate instructions in the appropriate use of our products and designed surgeries. Certain of our products require the use of specialized techniques which may not be covered in medical school curricula and / or product-specific knowledge. For example, metal implant implants such as screws or artificial joints, produce an artifact when magnetic resonance imaging, or MRI, is used to image the area in which the object resides. Our Qid Safety Technology microtransponder embedded in certain Motiva Implants contains metal and causes an artifact that can affect breast cancer screening using MRI, and this artifact is not present in other imaging modalities such as breast ultrasound and film or digital mammography. It is important that we educate physicians and patients on the risks associated with MRI artifacts and how to mitigate them if they choose to utilize Motiva Implants that contain a Qid microtransponder. Failure to provide adequate training and education could result in, among other things, unsatisfactory patient outcomes, patient injury, negative publicity or increased product liability claims or lawsuits against the company, any of which could have a material and adverse effect on our business and reputation. Claims against the company may occur even if such claims are without merit and / or no product defect is present, due to improper surgical technique, inappropriate use of our products, or other lack of awareness regarding the safe and effective use of our products. If we fail to educate physicians and patients about any of these factors, they may make decisions or conclusions regarding Motiva Implants without full knowledge of the risks and benefits or may view our Motiva Implants negatively. As part of our effort to educate and train plastic surgeons through our medical educational platform, we completed 239 and 192 and 201 medical training sessions worldwide during 2024 and 2023 and 2022, respectively. If we are unable to offer, or if we experience a delay in offering, medical training sessions, we may experience reduced or slower than expected adoption of our products. Although we offer virtual training sessions through our medical educational platform, any limited ability to provide in-person programs to surgeons may reduce the effectiveness of, and interest in, our medical education efforts. Commercial success of Motiva Implants in the United States or elsewhere depends on our ability to accurately forecast customer demand and manufacture sufficient quantities of product in the implant sizes that patients and physicians request, and to manage inventory effectively and the failure to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Manufacturing of silicone breast implants requires costly capital equipment and a highly skilled workforce. There is a significant lead time to build and certify a new manufacturing facility. Until 2017, we had one manufacturing facility in Costa Rica, causing occasional and we experienced inventory shortages from time to time that impaired our ability to meet market demand. In March 2017, our second manufacturing facility, also located in Costa Rica, facility became operational, and we received MDSAP certification, under the multi-country MDSAP protocol and began shipping saleable product products. Construction of a third facility started in 2021 and was completed in 2024. In August 2024, the smallest facility was shut down. Although we believe our current facilities give us adequate manufacturing capacity

to meet current demand, we have, in the past, been unable to fill all incoming orders. ~~We began construction of the third facility in Costa Rica during the third quarter of 2021. In July 2023, we announced the grand opening of the first phase of the Sulayöm Innovation Campus. We currently expect to commence manufacturing from the new facility in fiscal 2024. If this expansion is not completed in a timely manner, or if we are not able to get required regulatory approvals for the new facility, our ability to fill incoming orders may be adversely impacted. In addition, if we obtain FDA approval, we will likely need to obtain additional manufacturing capacity prior to any commercialization of our Motiva Implants in the United States.~~ If demand increases faster than we expect, or if we are unable to produce the quantity of goods that we expect with our current facilities, we may not be able to grow revenue at an optimal rate. There may be other negative effects from supply shortages, including loss of our reputation in the marketplace and a negative impact on our relationships with our distributors. On the other hand, if demand for our products declines, or if market supply surpasses demand, we may not be able to reduce manufacturing expenses or overhead costs proportionately. We have invested significantly in our manufacturing capacity in order to vertically integrate our business. If an increase in supply outpaces the increase in market demand, or if demand decreases, the resulting oversupply could adversely impact our sales and result in the underutilization of our manufacturing capacity, higher inventory carrying costs and associated working capital, changes in revenue mix, and / or price erosion, any of which would lower our margins and adversely impact our financial results.

Risks Related to Our Business, Industry and Operations We expect to incur losses for the foreseeable future, and our ability to achieve and maintain profitability depends on the commercial success of our Motiva Implants. We have incurred losses to date and expect to continue to incur losses for the foreseeable future. Sales of our Motiva Implants accounted for approximately **96 % and 95 % and 98 %** of our revenues for each of the years ended December 31, **2024 and 2023 and December 31, 2022 respectively**, and we expect our revenues to continue to be driven primarily by sales of these products. **We also** continue to incur significant research and development and general and administrative expenses related to our operations. We do not expect to be profitable in **2024-2025**, and in future years we expect to incur significant research and development expenses related to, among other things, the IDE clinical study of Motiva Implants in the United States. Investment in medical device product development, particularly clinical studies, is highly speculative. It entails substantial upfront capital expenditures and significant risk that any potential planned product will fail to demonstrate adequate accuracy or clinical utility. We may not be profitable for some time. As of December 31, **2023-2024**, we had an accumulated deficit of \$ **360,444.17** million. **We expect** In order to achieve and sustain profitability, our revenues from **these-our** products will need to grow beyond the levels we have achieved in the past. If physicians and / or patients do not perceive our products to be competitive in features and safety when compared to other products in the market, or if demand for our Motiva Implants or for breast implants in general decreases, we may fail to achieve sales levels that provide for future profitability. **Our ability to successfully market Motiva Implants and our other current and future offerings depends on numerous factors, including but not limited to:**

- the outcomes of current and future clinical studies of Motiva Implants to demonstrate our products' value in improving safety outcomes and / or patient satisfaction;
- acceptance of Motiva Implants as safe and effective by patients, caregivers and the medical community;
- an acceptable safety profile of Motiva Implants in the global market;
- whether key thought leaders in the medical community accept that such clinical studies are sufficiently meaningful to influence their or their patients' choices of product;
- maintenance of our existing regulatory approvals and expansion of the geographies in which we have regulatory approvals;
- designing commercially viable processes at a scale sufficient to meet anticipated demand at an adequate cost of manufacturing, and that are compliant with ISO 13485 Quality Management System requirements and / or good manufacturing practice, or GMP, requirements, as set forth in the FDA's Quality System Regulation, Brazilian and other international regulations;
- our success in educating physicians and patients about the benefits, administration and use of Motiva Implants;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the willingness of patients to pay out-of-pocket for breast augmentation and reconstruction procedures in the absence of coverage and reimbursement for such procedures;
- the success of our internal sales and marketing organization and the sales forces of our distributors; and
- continued demand for breast augmentation and reconstruction procedures using silicone implants, which may be adversely affected by events involving either our products or those of our competitors, including FDA warnings to patients regarding Breast Implant-Associated Anaplastic Large Cell Lymphoma, or BIA-ALCL and other lymphomas or cancers, including squamous cell carcinoma. Some of these factors are beyond our control.

If we are unable to continue to commercialize Motiva Implants and our other products, or unable to obtain a partner to commercialize them, we may not be able to produce any incremental revenues related to Motiva Implants and our other products. This would result in an adverse effect on our business, financial condition, results of operations and growth prospects. **Even if we are able to reach profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our planned products, market our current and planned products, or continue our operations.** Unfavorable global economic **and political** conditions, including slower growth or recession, inflation or, decreases in consumer spending power or confidence **or trade wars**, **have in the past, and could in the future,** adversely affect our business, financial condition or results of operations. Our results of operations **have been in the past, and could be in the future,** adversely affected by general conditions in the global economy and in the global financial markets, such as slower growth or recession, **adverse impacts on currency exchange rates**, continued inflation or decreases in consumer spending or confidence, **as well as changing political conditions**. A severe or prolonged economic downturn could result in a variety of risks to our business, including general economic pressure on our customers' patients. Elective aesthetic procedures, including breast augmentation, are typically not covered by insurance and are less of a priority than other items for those patients that have lost their jobs, are furloughed, have reduced work hours or have to allocate their cash to other priorities. As a result, adverse changes in the global economy, including as a result of ~~current~~ inflationary pressures, **higher-elevated** interest rates, geopolitical conflicts, including the Russia- Ukraine war and the Hamas- Israel conflict, **political instability** or macroeconomic

fallout from **significant** a potential-U. S. government **spending cuts** default on its debt, may cause consumers to reassess their spending choices and reduce demand for elective aesthetic procedures, which could have an adverse effect on our net sales and profitability. **Additionally, there is significant uncertainty about the future relationship between the United States and other countries with respect to trade policies, taxes, government regulations, and tariffs. The Trump administration has imposed additional tariffs on imported products and indicated it will continue to do so. The ultimate impact of tariffs will depend on various factors, including the scope, timing, amount, nature and implementation, but tariffs would likely have a negative impact on the global macroeconomy and on our business. In response to U. S. trade actions, certain countries may impose retaliatory actions against the U. S. These policies may lead to supply chain constraints and additional inflation, further increasing operational costs.** A weak or declining global economy **or disruptions caused by geopolitical uncertainty or regional political stability** could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers or distributors to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business. **We have incurred net operating losses..... planned products, or continue our operations.** If our available cash resources and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to sell equity or convertible debt securities, enter into a credit facility or another form of third- party funding, or seek other debt financing. We may need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our planned development and commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to our products and technologies. Our operations have consumed substantial amounts of cash since our inception, and we expect to incur significant expenses in connection with our planned research, development and product commercialization efforts. We believe that our available cash and cash from operations will be sufficient to satisfy our liquidity requirements for at least the next 12 months. If our available cash resources and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to sell equity or convertible debt securities, enter into a credit facility or another form of third- party funding, or seek other debt financing. However, we are subject to restrictive covenants under the Credit Agreement which restrict our ability to incur additional debt. Any failure to raise the funds necessary to support our operations or liquidity requirements may force us to delay, reduce or suspend our planned clinical trials, research and development programs, or other commercialization efforts. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic collaborations or partnership, or marketing, distribution or licensing arrangements with third parties, we may be required to do so at an earlier stage than would otherwise be ideal and / or may have to limit valuable rights to our intellectual property, technologies, products, or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our products. Our business depends on maintaining our brand and ongoing customer demand for our products and services, and a significant reduction in sentiment or demand could affect our results of operations. Our success depends on the reputation of our brands, which depends on factors such as the safety and quality of our products, our communication activities, including marketing and education efforts, and our management of our customer experience. Maintaining, promoting and positioning our brands is important to expanding our customer base. This will depend largely on the success of our education and marketing efforts and our ability to provide a consistent, high- quality customer experience. We may need to make substantial investments in the areas of education and marketing in order to maintain and enhance our brands. Ineffective marketing, negative publicity, significant discounts by our competitors, product defects and related liability litigation, failure to obtain regulatory clearance for our products, counterfeit products, unfair labor practices and failure to protect the intellectual property rights in our brands are some of the potential threats to the strength of our business. To protect our brands' status, we may need to make substantial expenditures to mitigate the impact of such threats. We believe that maintaining and enhancing our brands in the countries in which we currently sell our products, and in new countries where we have limited brand recognition, is important to expanding our customer base. If we are unable to maintain or enhance the strength of our brands in the countries in which we currently sell our products and in new countries, then our growth strategy could be adversely affected. If we fail to compete effectively against our competitors, many of whom have greater resources than we have, our revenues and results of operations may be negatively affected. Alternatives exist for Motiva Implants and for our other products, and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, medical device companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market silicone breast implants. We also face competition from manufacturers of saline-filled breast implants, and we see emerging competition from non- implant breast augmentation techniques such as hyaluronic acid injection and novel fat grafting methodologies. Any of these may present competitive barriers to Motiva Implants. Our leading competitors are large, multi- national companies with significant resources and capabilities. **Three of these companies, Sientra, Inc. (recently acquired by Tiger Aesthetics Medical), Mentor Worldwide LLC (a division of Johnson & Johnson) ; and Allergan plc (recently acquired by AbbVie Inc.)** have conducted large prospective clinical studies that started in the United States in 2002, 2000 and 1998, respectively, and they use this data extensively to promote their products. This can put us at a disadvantage when promoting our products to physicians and patients, even outside the United States. In addition, the significant financial and staff resources and brand recognition that our competitors possess mean they may be able to compete

with us regardless of the differentiating features of our products. If we are not successful in capturing market share, even outside the United States, or if physicians or patients do not perceive our products to be safer or more favorable, our revenues and / or our operating margins may be significantly impaired. In addition, manufacturers of competitive products may reduce prices for their competing products in an effort to gain or retain market share and undermine the value proposition that Motiva Implants might otherwise be able to offer to customers. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. These competitors may develop new technologies that are superior to our products or replace silicone. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with us in recruiting and retaining qualified technical and management personnel, establishing clinical study sites and patient registrations for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Pricing pressure from customers and our competitors may impact our ability to sell our products at prices necessary to support our current business strategies and future expansion. The industry environment for silicone implants and complementary products in certain international markets is price sensitive. In these markets, **including or in** the United States ~~if we are successful in obtaining the required regulatory approval to sell in the U. S. market~~, our competitors may adopt aggressive pricing strategies to intensify the competitive pricing pressure for breast implants. If we are not successful in educating customers or third-party payers on the differentiation of our Motiva Implants as compared to our competitors' products, customers may choose our competitors' products. Additionally, as more competitors introduce products that compete with ours, we may face additional pricing pressure that would adversely impact our future results. We expect to increase the size of our organization in certain jurisdictions and functions; as a result, we may encounter difficulties in managing our growth, which could disrupt our operations and / or increase our net losses. As of December 31, ~~2023~~ **2024**, we had ~~908~~ **1,018** employees. Unless it is necessary for us to make reductions to our workforce as a cost management strategy, over the next several years, we expect to experience growth in the number of our employees and the scope of our operations, principally in the areas of manufacturing and sales and marketing, and particularly as we ~~prepare~~ **continue to expand** our operations in the ~~anticipation~~ **wake** of obtaining approval from the FDA to commercialize our Motiva Implants in the United States. We also intend to continue to improve our operational, financial and management controls, reporting systems and procedures, which may require additional personnel. Such growth could place a strain on our administrative and operational infrastructure, and / or our managerial abilities, and we may not be able to make improvements to our management information and control systems in an efficient or timely manner. We may discover deficiencies in existing systems and controls. Many of these employees will be in countries outside of our corporate headquarters, which adds additional complexity. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage these activities. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require, in multiple countries; • managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; • managing additional relationships with various distributors, suppliers, and other third parties; • improving our managerial, development, operational and finance reporting systems and procedures; and • expanding our facilities. Our failure to accomplish any of these tasks could prevent us from growing successfully. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may also be exposed or subject to additional unforeseen or undisclosed liabilities as well as increased levels of indebtedness. In certain ~~large~~ **or anticipate engaging** markets, we engage in direct sales efforts. We may fail to maintain and develop our direct sales force, and our revenues and financial outcomes could suffer as a result. Furthermore, our direct sales personnel may not effectively sell our products. We have established a direct sales force for our business in Brazil ~~and United States~~, and we have implemented a direct sales strategy in several European countries. We have hired and will need to retain and motivate a significant number of sales and marketing personnel in order to support our anticipated growth in these countries. There is significant competition for quality personnel experienced in such activities, including from companies with greater financial resources than ours. If we are not successful in our efforts to continue recruiting, retaining, and motivating such personnel, we may not be able to increase our revenues, or we may increase our expenses in greater measure than our revenues, negatively impacting our operating results. ~~We are also working on creating a direct sales structure and strategy in certain markets. We are working to put in place the correct legal and business structures to comply with taxation and operational requirements. These structures may not ultimately be implemented or, if implemented, be successful or effective and may not be able to increase our revenues or improve our gross margins. In addition, our expenses or tax related costs may increase in greater measure than our revenues, negatively impacting our operating results.~~ We may be subject to substantial warranty or product liability claims or other litigation in the ordinary course of business that may adversely affect our business, financial condition and operating results. We face an inherent risk of product liability exposure related to the sale of Motiva Implants and ~~any planned~~ **our other** products in clinical studies. The marketing, sale and use of Motiva Implants and our ~~planned~~ **other** products could lead to the filing of product liability claims against us if someone alleges that our products failed to perform as designed or caused significant adverse events in patients. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. ~~If we cannot successfully~~ **In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend ourselves and could divert our management's attention, result in substantial damage awards** against claims that Motiva Implants ~~us, and harm~~ **or our reputation** ~~our planned products caused injuries, we may incur substantial liabilities~~. Regardless of merit or eventual outcome, liability claims may result in: • decreased

demand for **our products or** any planned products we may develop; • injury to our reputation and significant negative media attention; • withdrawal of patients from clinical studies or cancellation of studies; • significant costs to defend the related litigation and distraction to our management team; • substantial monetary awards to plaintiffs; • loss of revenue; and • the inability to commercialize any products that we may develop. We currently hold \$ 25 million in product liability insurance coverage, which may not be adequate to cover all liabilities we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Counterfeit products may be represented as ours, which could compete with our genuine products and may also expose us to risks associated with adverse events and product liability. We routinely see counterfeit versions of our major competitor's branded products in the marketplace, and we are aware of potential counterfeiting of our Motiva Implants. This is particularly common in emerging markets, where sensitivity to price is higher and regulatory enforcement is under-resourced. These counterfeit products are typically manufactured with significantly lower quality than the products they are claimed to be, and in some cases may be manufactured with silicones that are not medical grade. They may expose patients to significant adverse event risks, and there is a risk that certain adverse events with counterfeit products may be attributed to our genuine products. This could reduce demand for our products, result in negative publicity, or otherwise impact our business and the price of our shares. Negative publicity concerning our products or our competitors' products, including due to product defects, recalls and any resulting litigation, **or long-term safety impacts,** could harm our reputation and reduce demand for silicone breast implants, either of which could adversely impact our financial results and / or share price. The silicone breast implant industry has been the focus of significant regulatory and media scrutiny. Silicone breast implants were removed from the U. S. marketplace for a period in the 1990s and 2000s related to safety concerns. Certain patient advocacy groups exist to publicize real and perceived health risks associated with silicone breast implants and plastic surgery generally. Recently, some breast implant patients have begun to self- identify and report various symptoms that they believe are related to their breast implants; they refer to these symptoms as Breast Implant Illness, or BII, but BII is not an official medical diagnosis. Additionally, the activities of legislative bodies, regulatory agencies, physician organizations, and other groups may lead to publicity around the real and perceived risks to patients from silicone implants. The responses of potential patients, physicians, the news media, legislative and regulatory bodies and others to information about complications or alleged complications of our products or our competitors' products, or products liability litigation against us or our competitors, could materially reduce market acceptance and patient demand for our products, or could, even in the absence of a change in demand, negatively impact our business and reputation and negatively impact our financial condition, results of operations or the market price of our common shares. In addition, activity of this type could result in an increase in the number or size of product liability claims, which would adversely affect our business, financial results, and / or the price of our shares. **Recent news-News** coverage **in recent years** has called into question the long-term safety of breast implants and reports of breast implant-associated anaplastic large cell lymphoma linked to our competitors' products which have led to regulatory actions regarding macrotextured devices in several countries and the worldwide recall of one of our competitor's macrotextured implants and tissue expanders. These events and reports of other forms of cancer, including squamous cell carcinoma and various lymphomas, from breast implant products may lead to a reduction in the demand for silicone breast implants and could adversely affect our business. Women with breast implants have reported higher rates, as compared to the general population, of breast implant-associated anaplastic large cell lymphoma, or BIA-ALCL, an uncommon type of cancer affecting cells of the immune system. In January 2011, the FDA indicated that there was a possible association between certain saline and silicone gel-filled breast implants and higher rates of BIA-ALCL, with the causal links neither yet understood nor confirmed. In March 2015, France's National Cancer Institute, or NCI, noted that there is a clearly established link between anaplastic large cell lymphoma and certain breast implants, which is referred to as breast implant-associated ALCL, or BIA-ALCL. The NCI noted in that report that most of the reported cases occurred in women with textured implants. In August 2017, the FDA updated its advisory on BIA-ALCL and subsequently requested all breast implant manufacturers to revise their physician and patient labeling with the most current information. The August 2017 update described BIA-ALCL as "rare" and stated "we have strengthened our understanding of this condition and concur with the World Health Organization designation of BIA-ALCL as a rare T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and **the** lack of global implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces." The FDA noted it does not recommend prophylactic breast implant removal in a patient without symptoms or other abnormalities. In March 2018, the FDA further updated its advisory on BIA-ALCL stating "we are reporting that we are aware of 414 total cases of BIA-ALCL. Additionally, studies reported in medical literature estimate that the lifetime risk of developing BIA-ALCL for patients with textured breast implants ranges from 1 in 3, 817 to 1 in 30, 000." The FDA noted that the update did not change the agency's recommendation and that choosing to obtain a breast implant is a personal decision that patients and providers should make with the most complete information available. In the fourth quarter of 2018, following the non-renewal of its textured breast implant CE Mark licenses in Europe, Allergan plc suspended sales of textured breast implants in Europe and withdrew its remaining textured breast implants on the market within Europe. On February 6, 2019, the FDA further reported that as of September 2018, the agency had received a total of 660 medical device reports regarding BIA-ALCL cases since 2010. Of the 660 reports, the FDA's analysis suggested that there were 457 unique cases of BIA-ALCL, including nine patient deaths. Additionally, on February 12, 2019, Health Canada confirmed that as of January 1, 2019, it had received reports of 22 confirmed and 22 suspected Canadian cases of BIA-ALCL and that it would be updating its safety review of BIA-ALCL in Spring 2019. In April 2019, the Agence Nationale de Sécurité du Médicament et des Produits de Santé, or ANSM, the regulatory authority in France, announced that 59 cases of BIA-ALCL had been reported in France since 2011 and banned several types of macrotextured and polyurethane implants linked to BIA-ALCL. Between February and September 2019, authorities from Australia, Colombia,

Canada, South Korea and Singapore announced similar bans. In July 2019, the FDA requested that Allergan plc recall its Biocell® textured implants in the U. S. market and Allergan subsequently announced the global recall of its Biocell® textured breast implants and tissue expanders. In the announcement, the FDA noted that it had reviewed 573 unique cases globally of BIA-ALCL, including 33 patient deaths, of which 12 of the 13 known deaths were attributed to Biocell® implants. The FDA further noted that it will continue to monitor the incidence of BIA-ALCL across other textured and smooth breast implants and tissue expanders as well as other devices intended for use in the breast. The FDA subsequently identified the recall as a Class I recall in September 2019 and stated that use of the recalled devices may cause serious injuries and death. As the BIA-ALCL risk continues to become more highly publicized, this could have a significant negative impact on demand for breast implants globally, including our Motiva Implants. In August 2020, the FDA updated its analysis of medical device reports of breast implant illness and breast implant associated lymphoma. In this update, the FDA updated the table on the agency's BIA-ALCL webpage to include a total of 733 unique cases and 36 patient deaths globally as of January 5, 2020, which reflect an increase of 160 new cases and 3 deaths since the early- July 2019 update. In September 2020, the FDA released finalized guidance on breast implant labeling recommendations, including the addition of a boxed warning, a patient decision checklist, material and device descriptions, implant rupture screening recommendations and a patient device card. In October 2021, the FDA took several additional actions to strengthen breast implant risk communication, including restricting the sale and distribution of breast implants to only health care providers and facilities that provide information to patients using the patient decision checklist. The FDA also approved new labeling for all legally marketed breast implants that includes a boxed warning, a patient decision checklist, updated silicone gel- filled breast implant rupture screening recommendations, a device description with a list of specific materials, and a patient device card. In September 2022, the FDA informed the public about reports of cancers, including squamous cell carcinoma, or SCC, and various lymphomas, in the scar tissue (capsule) that forms around breast implants different from the lymphomas described in previous FDA communications as BIA-ALCL. In March 2023, the FDA provided updated information about SCC, noting it has received 24 reports of SCC related to breast implants, but that this does not necessarily represent cancer incidence because of potential underreporting or duplicated reports. The FDA noted that, while the agency believes the occurrences of SCC or various lymphomas in the capsule around the breast implant to be rare, health care providers and people who have or are considering breast implants should be aware that cases have been reported to the FDA and in the literature. We do not produce the types of rough textured implants that have been involved in these reports. To date, no cases of BIA-ALCL or SCC have been reported in patients with Motiva Implants. Furthermore, there have been no reported cases of BIA-ALCL in patients with smooth implants with no history of previously having a textured device. Future clinical studies or clinical experience may indicate that breast implants expose potentially genetically predisposed patients to greater risks of BIA-ALCL, which may reduce demand for silicone implants generally, expose us to product liability claims, as well as to class actions and other lawsuits. These impacts may occur in the absence of any specific linkage with our products. Moreover, if cases of BIA-ALCL, SCC, or other complications are discovered in the future and / or are reported in patients with Motiva Implants, we could be subject to mandatory product recalls, suspension or withdrawal of our regulatory licensure for sale in one or more countries, and significant legal liability. Any of these may have an adverse effect on our business or operating results, or a negative impact on our share price. The loss of members of our executive management team or other employees, or other turnover in our management team, could adversely affect our business. Our success in implementing our business strategy depends largely on the skills, experience and performance of members of our executive management team and other key employees, including Juan José Chacón Quirós, our Chief Executive Officer **who is set to retire in March 2025, Peter Caldini, our President and upcoming Interim Chief Executive Officer**, Roberto de Mezerville, our Chief Technology Officer, Rajbir Denhoy, our Chief Financial Officer, and Ross Mansbach, our General Counsel and Chief Human Resources Officer. The collective efforts of each of these persons, and others working with them as a team, are critical as we continue to develop our tests and technologies and pursue our research and development and sales programs. In addition, we have experienced significant changes in our executive leadership in recent years, including in our **General Counsel and Chief Executive Officer**, Chief Operating Officer **and General Counsel** positions. As a result of the difficulty in locating qualified new management and other key employees, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. In addition, changes to strategic or operating goals, which can often times occur with the appointment of new executives and directors, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. Executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management turnover inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. We do not have "key person" life insurance on our senior executives, and the loss of any of the key team members would have a negative impact to our business and financial results. In addition, the job market in Costa Rica and other locations in which we operate has recently become more competitive and we are competing for talent with major multinational corporations which have significantly more resources than us, and we may find new difficulties in retaining our most talented employees. In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us. We have made multiple acquisitions in the past, and in the future, we may acquire other businesses, form joint ventures or make investments in other companies or technologies. If we are not successful in integrating these businesses, as well as identifying and controlling risks associated with the past operations of these businesses, we may incur significant costs, receive penalties or other sanctions from various regulatory agencies and / or incur significant diversions of management time and attention. We believe our business

growth will be enhanced if we continually seek opportunities to enhance and broaden our product offerings. As part of our business strategy, we may pursue acquisitions or licenses of assets, or acquisitions of businesses. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution resources. We have acquired companies and / or assets and licensed assets in a variety of countries, including Brazil and several European countries. We may do more of these types of transactions in the future and may also form strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have an adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company may also disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction, we may choose to issue common shares as consideration, which would dilute the ownership of our shareholders. If the price of our common shares is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our shares as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. ~~We do not know whether~~ **Integrating any business, product or technology we will acquire could be able to successfully integrate any acquired** ~~expensive and time-consuming, disrupt our ongoing~~ **business, product impact or our technology. The liquidity, and / or distract our management and its** ~~success of any given acquisition may also depend on our ability to retain any key employees related~~ **to the acquired** ~~thereto, and we may not be successful at retaining or integrating such key personnel.~~ ~~Integrating any business, product or technology we acquire could be expensive and time-consuming, disrupt our ongoing business, impact our liquidity, and / or distract our management.~~ If we are unable to integrate any acquired businesses, products or technologies effectively, our business may suffer. Whether as a result of unsuccessful integration, unanticipated costs, including those associated with assumed liabilities and indemnification obligations, negative accounting impact, or other factors, we may not realize the economic benefits we anticipate from acquisitions. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses. We have significant exposure to the economic and political situations in emerging market countries, and developments in these countries could materially impact our financial results, or our business more generally. Many of the countries in which our products are sold are emerging markets. Our global growth strategy contemplates the expansion of our existing sales activities in Latin America, Europe, the Middle East, and Asia-Pacific region as well as North America. Our exposure to emerging markets has increased in recent years, as have the number and importance of our distributor arrangements. Economic and political developments in Brazil and other emerging markets, including economic crises, currency inflation, or political instability, have had in the past, and may have in the future, a material adverse effect on our financial condition and results of operations. Moreover, as these markets continue to grow, competitors may seek to enter these markets and existing market participants will likely try to aggressively protect or increase their market shares. Increased competition may result in price reductions, reduced margins and our inability to gain or hold market share, which could have an adverse effect on our financial condition and results of operations. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our liquidity and financial performance. Bank failures, 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. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank Corp. and Silvergate Capital Corp. were each swept into receivership. We do not maintain balances with, and are not a borrower under or party to any credit agreement, material letter of credit or any other such instruments, with any financial institution currently in receivership. However, we regularly maintain cash balances at third-party financial institutions in excess of the FDIC standard insurance limit, with balances concentrated at a small number of financial institutions. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, or which we do business with, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U. S. or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. In addition, if any of our partners or parties with whom we conduct business are unable to access funds due to the status of their financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. 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. Our results of operations **have been in the past, and could be in the future, adversely** affected by fluctuations in currency rates. We present our results of operations in U. S. dollars, which is our reporting currency. However, as of December 31, **2023-2024**, the majority of our revenues are denominated in currencies other than the U. S. dollar- primarily the euro, the Brazilian real, and the British pound. As of

December 31, ~~2023~~ **2024**, the majority of our expenses are denominated in U. S. dollars or in Costa Rican colones, which are linked to the U. S. dollar. In the future, we expect to have significant revenues and expenses denominated in these non- U. S. currencies. As such, unfavorable fluctuations in currency exchange rates have had, and in the future could continue to have, an adverse effect on our results of operations. Because our consolidated financial statements are presented in U. S. dollars, we must translate revenues, expenses and income, as well as assets and liabilities, into U. S. dollars at exchange rates in effect during or at the end of each reporting period. Therefore, changes in the value of the U. S. dollar in relation to the British pound, the euro, Costa Rican colones and the Brazilian real will affect our revenue, cost of goods, and operating expenses as well as the value of balance sheet items originally denominated in other currencies. These changes would cause our growth in consolidated earnings stated in U. S. dollars to be higher or lower than our growth in local currency when compared against other periods. For example, the weakening of the euro for the majority of fiscal 2022 **and of the Brazilian real in 2024** had a negative effect on our ~~European~~ revenue **in those respective years**. We do not currently engage in currency hedging arrangements to protect us from fluctuations in the exchange rates of the euro and other currencies in relation to the U. S. dollar (and / or from inflation of such currencies), and we are exposed to material adverse effects from such movements. We cannot predict any future trends in rates of inflation or exchange rates of other currencies against the U. S. dollar, and there can be no assurance that any contractual provisions will offset their impact, or that any future currency hedging activities will be successful. Continued international expansion of our business will expose us to business, regulatory, political, operational, financial and economic risks associated with doing business internationally. Our products are commercially available in 86 countries, and we operate subsidiaries in the United States, Costa Rica, Brazil, and several European countries. Our business strategy contemplates continued international expansion, including partnering with medical device distributors, and introducing Motiva Implants and other planned products outside the United States. The sale and shipment of our products internationally, as well as the purchase of components from international sources, subjects us to potential trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non- compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export or import privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, marketing and sales activities. In addition, several of the countries in which we sell our products or conduct our operations are, to some degree, subject to political, economic or social instability. Doing business in Costa Rica and other countries outside the United States involves a number of other risks, including: • ~~compliance with the free zone regime regulations under which the manufacturing sites operate;~~ • ~~different regulatory requirements for device approvals in international markets;~~ • multiple, conflicting and changing laws and regulations such as tariffs and tax laws, export and import restrictions, employment laws, environmental laws, regulatory requirements, **price controls, reimbursement schemes** and other governmental approvals, permits and licenses ; • ~~potential failure by us or our distributors to obtain and / or maintain regulatory approvals for the sale or use of our products in various countries;~~ • difficulties in managing global operations; • logistics and regulations associated with shipping products, including ~~infrastructure conditions~~ **interruptions resulting from natural or other disasters including earthquakes, volcanic activity, hurricanes, floods and fires,** and transportation delays; • limits on our ability to penetrate international markets if our distributors do not execute successfully ; • ~~governmental price controls, differing reimbursement regimes and other market regulations;~~ • financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to currency exchange rate fluctuations; • reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available; • economic weakness, **currency fluctuations,** political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions ; • ~~the British exit from the EU, including with respect to its effect on the value of the British pound relative to other currencies;~~ • failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti- bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities; • failure to comply with restrictions on the ability of companies to do business in foreign countries, including restrictions on foreign ownership of telecommunications providers imposed by the U. S. Office of Foreign Assets Control; • failure to comply with evolving reporting expectations on environmental, social and governance issues; • unexpected changes in tariffs, trade barriers and regulatory requirements ; • ~~compliance with tax, employment, immigration and labor laws;~~ • taxes, including withholding of payroll taxes; • ~~currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;~~ • workforce uncertainty in countries where labor unrest is more common than in the United States; **and** • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad ; **and** • ~~business and shipping interruptions resulting from natural or other disasters including earthquakes, volcanic activity, hurricanes, floods and fires.~~ Any of these risks, if encountered, could harm our future international expansion and operations and, consequently, have an adverse effect on our financial condition, results of operations and cash flows. Any disruption at our existing facilities could adversely affect our business and operating results. Our headquarters are located in Costa Rica, and all of our main manufacturing activities are conducted in ~~two~~ **the** ISO- 13485 and GMP compliant manufacturing facilities in Costa Rica through Establishment Labs, S. A. ~~A third~~ **The newest** facility in Costa Rica ~~is under construction~~ **was completed in June 2024** and ~~is currently expected to commence~~ **commenced** manufacturing in **the second half of** fiscal 2024. Despite our efforts to maintain and safeguard our manufacturing facilities, including acquiring insurance and adopting maintenance and health and safety protocols, vandalism, terrorism or a natural or other climate- related disaster, such as earthquake, volcanic activity, fire or flood, could damage or destroy our inventory of finished goods, cause substantial delays in our operations and manufacturing, result in the loss of key information and cause us to incur additional expenses. Our insurance may not cover our losses in any particular

case. In addition, regardless of the level of insurance coverage, damage to our facilities may have an adverse effect on our business, financial condition and results of operations. Fluctuations in insurance costs and availability, and future insurance requirements could adversely affect our profitability or our risk management profile. We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which would adversely affect our results of operations or financial condition.

Risks Related to Manufacturing and Other Third- Party Relationships Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business, and could expose us to liability if our use of such hazardous materials causes injury. Our manufacturing processes currently require the controlled use of potentially harmful chemicals, including highly flammable solvents. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. These are particularly stringent in California, where Avantor, one of our key suppliers, is located. The cost of compliance with these laws and regulations may become significant and could have an adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines. We rely on third parties to conduct certain components of our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies, which could interfere with or delay our ability to obtain regulatory approval or commercialize our products. We rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to perform various functions for our clinical trials. These service providers may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. We are required to collect and provide financial disclosure notifications or certifications for our clinical investigators to the FDA. If the FDA concludes that a financial relationship between us and a clinical investigator has created a conflict of interest or otherwise affected interpretation of the trial, the FDA may question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the International Council for Harmonization, or ICH, and the FDA require us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical studies to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our planned products and will not be able to, or may be delayed in our efforts to, successfully commercialize our planned products. We rely on a single- source, third- party supplier for medical- grade long- term implantable silicone, which is the primary raw material used in our Motiva Implants. **As has occurred in the past, if** this supplier were to increase prices for this raw material over time or experience interruptions in its ability to supply us with this raw material, our business, financial condition and results of operations could be adversely affected. We rely on Avantor ~~Inc. (formerly NuSil Technology, LLC), or Avantor,~~ as the sole supplier of medical- grade silicone used in our Motiva Implants as well as other products that we manufacture under contract to other customers. To our knowledge, Avantor is the only supplier of such raw materials with the appropriate filings with the FDA and other regulatory bodies to enable the manufacturing of products with our requirements. Avantor supplies our major competitors with raw material as well, and at least two of these are larger- volume customers of Avantor than we are. If Avantor becomes unable or unwilling to supply sufficient quantities of medical- grade silicone of the specifications required for our products, **or if Avantor increases prices further in the future,** we may not be able to replace this supply source quickly, or at all. Similarly, ~~they it~~ **they it** may become unable or unwilling to manufacture our needed raw materials in compliance with regulatory requirements, or ~~their its~~ **their its** manufacturing facilities may not be able to maintain compliance with regulatory requirements. Any replacement supplier would have to be qualified with the relevant regulatory authorities, which is an expensive and time- consuming process during which we may experience an interruption in our manufacturing operations. We may also be unsuccessful in negotiating favorable terms with such a supplier. Any of these contingencies would likely affect the financial results of our operations and may have a negative impact on our share price. In particular, if we are not able to establish a replacement vendor for our medical- grade silicone, we would be unable to manufacture our Motiva Implants as well as other products that we manufacture under contract to other customers until such time as a replacement vendor is identified, which would likely significantly affect the financial results of our operations and have a significantly negative impact on our share price. In addition, our relationship with Avantor involves other risks, including but not limited to the following:

- it may not be able, or willing, to manufacture silicone raw materials with our agreed- upon specifications;
- it may not be able, or willing, to manufacture our needed raw materials in compliance with regulatory requirements, or our its manufacturing facilities may not be able to maintain compliance with regulatory requirements;
- it may not be able to supply sufficient quantities of each

raw material quickly enough for us to respond to rapid increases in demand; • it may unintentionally convey information to our competitors that is helpful in understanding our proprietary compositions and other trade secrets of our manufacturing processes; • we may be subject to price fluctuations if we fail to meet certain minimum order requirements, or if our existing contract expires or is renegotiated; • it may lose access to critical services and components, resulting in interruption in manufacture or shipment of medical- grade silicone; • its facilities may be affected by earthquakes, wildfires, mud slides or other natural disasters, which could delay or impede production of our raw materials; • we may be required to obtain regulatory approvals related to any change in our supply chain; • Avantor may wish to discontinue supply of products to us due to its existing relationships with our competitors; • Avantor may stop supply and claim ownership of intellectual property on materials associated with future products; • Avantor or its parent entity may encounter financial or other hardships unrelated to our demand for products, which could negatively impact their ability to fulfill our orders and support our regulatory approvals; and • disputes may arise over the terms of the Master Supply Agreement, by and between the Company and Avantor, dated May 13, 2022. Various factors outside our direct control, including the reliance on single- source suppliers, may adversely affect manufacturing and supply of our Motiva Implants and other products. We currently manufacture Motiva Implants at our facilities in the Coyoil Free Zone, Alajuela, Costa Rica, under the multi- country MDSAP protocol. Our Qid Safety Technology microtransponders are manufactured by contract manufacturers with final testing and packaging at a manufacturing supplier facility in Regensburg, Germany, with additional inspection of the units at our facilities in Coyoil, Costa Rica, prior to approval for inclusion in Motiva Implants. If demand for our current products and our planned products increases more rapidly than we anticipate, or if we secure regulatory approval to commercialize our products in additional geographies, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. The manufacture of these products in compliance with ISO standards and the FDA's regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations. **Further, any prolonged disruption in a supplier's operations could have a significant negative impact on our ability to manufacture and deliver products in a timely manner and as a result, our business, financial condition and results of operations could be adversely affected.** We currently purchase components for the Qid Safety Technology microtransponders under purchase orders and do not have long- term contracts with most of the suppliers of the materials included in these products. We rely on Avantor as the sole supplier of medical- grade silicone used in our Motiva Implants as well as other products that we manufacture under contract to other customers. See the risk factor above titled " We rely on a single- source, third- party supplier for medical- grade **long- term implantable** silicone, which is the primary raw material used in **our Motiva Implants. As has occurred in these-- the products. If past, if** this supplier were to increase prices for **these this raw materials- material** over time or experience interruptions in **their-its** ability to supply us with this raw material, our business, financial condition and results of operations could be adversely affected. " In addition, the suppliers of certain packaging components and the surgical tools that we sell with Motiva Implants, including the cannulas, retractors, and insertion sleeves, are all purchased by us from single- source suppliers. If our single- source and other suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us at all or on commercially reasonable terms, we would need to identify and initiate relationships with alternative suppliers, if possible. We could experience delays in manufacturing our products or the interruption of the availability of Motiva Implants or our other products for sale, while finding another acceptable supplier, which would impact our business, financial condition and results of operations. Even if such alternative suppliers are available on commercially reasonable terms, the **changes could also result in increased costs..... ability to sell Motiva Implants. The** inclusion of substitute components or products must meet our specifications and could require us to qualify the new supplier with the appropriate regulatory authorities. The added time and cost to arrange for alternative suppliers could have a material adverse effect on our business. New manufacturers of any current or planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the design and method of manufacturing the planned product. Obtaining the necessary FDA or international approvals or other qualifications under applicable regulatory requirements and ensuring non- infringement of third- party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us .The manufacturing,sterilization and distribution of our Motiva Implants and other products are technically challenging.Changes that our suppliers may make,or additional requirements from regulatory agencies,are outside of our direct control and can have an impact on our processes,on quality,and on the successful delivery of products to our customers.Mistakes and mishandling are not uncommon and can affect supply and delivery.Some of these risks include:• failure to complete sterilization on time or in compliance with the required regulatory standards;• transportation and import and export risk,particularly given the global nature of our supply and distribution chains;• delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;• natural or other disasters,labor disputes,financial distress,lack of raw material supply,issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers;• latent defects that may become apparent after products have been released and that may result in a recall of such products;• contamination of our raw materials or manufactured products;and • inclusion of vendors of raw materials not in compliance with ISO- 13485 requirements . A substantial proportion of our sales are through exclusive distributors, and we do not have direct control over the efforts these distributors may use to sell our products. If our relationships with these third- party distributors deteriorate, or if these third- party distributors fail to sell our products or engage in activities that harm our reputation, or fail to adhere to medical device regulations, our financial results may be negatively affected. Historically, our sales model has been to sell primarily through distributors rather than through our own sales force, with the notable exception of

Brazil and several European countries where we are selling directly, but, in the future, we may utilize a hybrid sales model that includes both distributors and a direct sales effort. We believe that our reliance on distributors improves the economics of our business, as we do not carry the high fixed costs of a direct sales force in many of the countries in which our Motiva Implants are sold. If we are unable to maintain or enter into such distribution arrangements on acceptable terms, or at all, we may not be able to successfully commercialize our products in certain countries. Furthermore, distributors can choose the level of effort that they apply to selling our products relative to others in their portfolio. The selection, training, and compensation of a distributors' sales personnel are within their control rather than our own and may vary significantly in quality from distributor to distributor. In addition, although our contract terms require our distributors to comply with all applicable laws regarding the sale of our products, including anti-competition, anti-money laundering, and sanctions laws, we may not be able to ensure proper compliance. If our distributors fail to effectively market and sell our products in full compliance with applicable laws, our results of operations and business may suffer.

Risks Related to Public Health Crises Pandemics, epidemics, or other public health crises may adversely affect our business and financial results in the future, as was the case with the COVID-19 pandemic in recent years. As was the case with the COVID-19 pandemic, which resulted in a material disruption of our operations in fiscal 2020 and to a lesser degree in fiscal 2021, we are subject to risks associated with pandemics, epidemics or other public health crises. The full extent to which any pandemic, epidemic, or public health crisis may, directly or indirectly, impact our business, results of operations and financial condition, including our sales, expenses, supply chain integrity, manufacturing capability, research and development activities, and employee-related compensation, is highly uncertain and will depend on future developments that are also highly uncertain and cannot be predicted with reasonable accuracy at this time, including, without limitation:

- the contagiousness or virulence of the virus, disease or other condition giving rise to the pandemic, epidemic or public health crisis;
- the scope and length of any governmental or other restrictions implemented to reduce the spread of virus, disease or other condition giving rise to the pandemic, epidemic or public health crisis or other actions required or recommended to contain or treat infected individuals;
- the deferral of procedures using our products or other adverse impact on patients' willingness to undergo procedures in which our products could be used during or following any pandemic, epidemic or other public health crisis;
- volatility in the global capital markets, impacting access to and cost of capital;
- disruptions in the manufacture and distribution of our products and in our supply chain;
- delays in clinical trials;
- disruptions or restrictions on the ability of many of our employees, and of third parties on which we rely, to work effectively, including "stay-at-home" orders and similar government actions;
- temporary closures of our facilities and of the facilities of our customers and suppliers; and
- other direct and indirect economic impacts, both domestically and abroad, of a pandemic, epidemic, or public health crisis as a result of any or all of the foregoing, including actions taken by local, state, national and international governmental agencies, whether such impact affects customers, suppliers, or markets generally.

Risks Related to Intellectual Property and Data Security If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position. In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information, however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the United States. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have an adverse effect on our business. If we are not able to obtain and maintain intellectual property protection for our products and technologies, or if the scope of our patents is not sufficiently broad, we may not be able to effectively maintain our market leading technology position. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products. The patent position of medical device and diagnostic companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. **The** In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. **Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of other countries may not protect our rights to the same extent as the laws of the U. S.** Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we or were the first to file for patent protection of such inventions. **In addition, changes in either the patent laws or interpretation of the**

patent laws in the United States and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of other countries may not protect our rights to the same extent as the laws of the U. S. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. **Further, We may not be able to protect or enforce our intellectual property rights throughout the world. Filing filing**, prosecuting and defending patents on all of our planned products throughout the world may be prohibitively expensive to us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing. **Many companies have encountered significant problems in The medical device industry is characterized by patent litigation, and we could become subject to litigation or other proceedings to protect and defend or enforce our intellectual property rights that in international jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive-costly, result in the diversion of management's time consuming and efforts, require us to pay damages or prevent us from marketing or our unsuccessful-existing or future products.** Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. **Our competitors or other third parties may also assert infringement claims against us based on existing or future intellectual property rights.** In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. **Interference or derivation proceedings provoked by third parties or brought by the U. S. Patent and Trademark Office, or USPTO, or any other patent authority may also be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We may become involved in proceedings, including oppositions, interferences, derivation proceedings, inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain.** An adverse result in any litigation or other legal proceeding could put one reduce the scope of, or more invalidate, important patents-property-patent rights with respect, allow third parties to commercialize our technology or products and compete directly with technology. Third parties may assert infringement claims against us based on existing, without payment to us, or future intellectual property result in our inability to manufacture or commercialize products without infringing third-party patent rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. **Even if we were able to obtain a license, it at risk of being invalidated all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving or our interpreted narrowly competitors access to the same technologies licensed to us and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees from their normal responsibilities.** Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. **Interference or derivation proceedings provoked by third parties or brought by the U. S. Patent and Trademark Office, or USPTO, or any other patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We may become involved in proceedings, including oppositions, interferences, derivation proceedings, inter partes reviews, patent nullification proceedings, or re-examinations, challenging our**

patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. If we are unable to resolve these disputes, we could lose valuable intellectual property rights. **Even if resolved in our favor..... operations, which could harm our business.** Many of our employees were previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors 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 these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above. **Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities.** In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the **market** price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce **our the** resources available for development activities. **We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our or any future sales, marketing competitors may be able to sustain the costs of such litigation or distribution activities proceedings more effectively than we can because of their substantially greater financial resources.** Uncertainties resulting from the initiation and continuation of **litigation or other intellectual property related litigation or other** proceedings could have **an a material** adverse effect on our ability to compete in the marketplace. Obtaining and maintaining 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. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid by us to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. The USPTO and various non-U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business. If we fail to comply with our obligations in our intellectual property agreements, we could lose intellectual property rights that are important to our business. We are a party, and expect to become party in the future, to certain intellectual property agreements that impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, any licensor may have the right to terminate such agreements, in which event we may not be able to develop and market any product that is covered by such agreements. Termination of such agreements, or reduction or elimination of our rights under such agreements, may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could harm our business and financial condition. The risks described elsewhere in this Annual Report on Form 10-K pertaining to our intellectual property rights also apply to any intellectual property rights that we may license, and any failure by us or any future licensor to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. Our information systems, or those used by third parties which we rely on, may fail, be impacted by cybersecurity incidents, suffer other security **breaches incidents** or be vulnerable to other forms of attack or damage. The operation of our business depends on our information systems and, in some cases, the information systems used by third parties. We rely on our information systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Despite the implementation of security measures, our information systems, or those used by third parties which we rely on, are vulnerable to a variety of cybersecurity incidents and cybersecurity threats, as well as other forms of attack or damage, including damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security **breaches incidents**, data corruption, and cyberattacks. Cybersecurity incidents can include, but are not limited to, computer viruses, computer denial-of-service attacks, phishing attacks, ransomware attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, social engineering or impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. **Further, we rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, enterprise cloud solutions, encryption and authentication technology, employee email, and other similar functions. Although we prefer third parties that are SOC 1 compliant or adhere to other related regulations, our ability to monitor their information security practices is limited, and they may not have adequate security measures in**

place. They may also experience unexpected power losses, computer system failures, or data network disruptions, negatively impacting the systems or solutions we depend on. If our third-party providers face a security incident or other interruptions, or if there is a flaw or failed software update in the third-party software used in our systems, our information systems may become disabled or inaccessible. This could limit access to our data and business information, potentially causing significant disruptions to our operations. Attacks upon information systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, information systems change frequently, including from emerging technologies, such as advanced forms of AI and quantum computing, and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience cybersecurity incidents or other incidents security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate cybersecurity incidents or threats due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we have not experienced any material cybersecurity incident or other system failure or security breach to our knowledge to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, leading to increased costs, product shortages or lost revenues. To the extent that any cybersecurity incident, security breach or other attack or damage to our information systems were to result in a loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, we could incur liability and the further development and commercialization of our current and future products could be delayed. For example, the loss of data from completed, ongoing or future studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, any such cybersecurity incident, security breach, or other attack or damage could harm our reputation, erode customer confidence in the effectiveness of our security measures, and negatively impact our ability to attract new customers. Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business. In the ordinary course of our business, we collect and store sensitive data, including legally protected patient health information, credit card information and personally identifiable information. We collect this kind of information on our customers for purposes of servicing potential warranty claims and for post-marketing safety vigilance. These data Data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act 2009, or For ARRA example, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's protected health information by certain health care providers, health care clearinghouses, and health insurance plans, collectively referred to as covered entities, and their business associates, persons or entities that perform a function or provide specified services on behalf of a Covered Entity that involve the creation, use, maintenance or transmission of protected health information. The HIPAA amendments also impose imposes compliance breach notification obligations and corresponding penalties for breaches non-compliance on individuals and entities that perform a function or provide specified services to health care providers and other covered entities, collectively referred to as business associates. Most recently, on December 10, 2020, HHS issued a Notice of Proposed Rulemaking, which if finalized, would make changes to some of HIPAA's regulatory requirements, which would impact us, to the extent we are a business associate. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's protected health information, including under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements to federal regulators and in some cases for individuals whose protected health information has been inappropriately accessed or disclosed, notification to relevant media outlets. Most states also have breach notification requirements to federal regulators affected individuals and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U. S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the protected health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure may constitutes constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the FTCA, 15 U. S. C § 45 (a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data Health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing At the state level, several U. S. states have proposed and passed consumer privacy laws. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act, (" CCPA") includes certain transparency and other requirements to protect personal data and grants California consumers with certain rights regarding their personal information data. In addition, California consumers have the right to bring a private right of action in connection with data security incidents involving certain elements of personal data. Additionally, other jurisdictions, such as Virginia, Colorado, Utah, and Connecticut, have enacted similar legislation and / or regulations. Health-specific consumer privacy laws were also passed in multiple states, including Washington and Nevada. These laws and regulations are constantly evolving and may impose limitations on our business activities. Moreover, as a result of the broad scale release and availability of Artificial

Intelligence (AI) technologies such as generative AI, there is similar to what is required by a global trend towards more regulation (e. g., the HPPAA-EU AI Act and AI laws passed in U. S. states) to ensure the ethical use, privacy, and Security **Rule of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future**. Many foreign countries and governmental bodies, including the EU, UK, Canada, Australia and other relevant jurisdictions, have laws and regulations concerning the collection and use of personal or sensitive data obtained from their residents or by businesses operating within their jurisdiction. For example, the EU / European Commission recently adopted the General Data Protection Regulation, including as implemented in the UK, or the GDPR, effective on May 25, 2018, that supersedes current EU data protection legislation, imposes more stringent EU data protection requirements and provides for greater penalties for noncompliance. **It** The GDPR regulates the processing of personal data and places certain obligations on the processing of such personal data including ensuring the lawfulness of processing personal data (including obtaining valid consent of the individuals to whom the personal data relates, where applicable), the processing details disclosed to the individuals, the adequacy, relevance and necessity of the personal data collected, the retention of personal data collected, the sharing of personal data with third parties, the transfer of personal data out of the European Economic Area / UK to third countries including the US, contracting requirements (such as with clinical trial sites and vendors), the use of personal data in accordance with individual rights, the security of personal data and security breach / incident notifications. Non-compliance with the EU / UK GDPR can trigger steep fines for the most serious breaches of up to € 20 million or 4 % of total worldwide annual revenues, whichever is higher. Given the breadth and depth of changes in data protection obligations, meeting the EU / UK GDPR's requirements requires time, resources and a review of the technology and systems currently in use against the EU / UK GDPR's requirements. We may be at risk of enforcement actions taken by certain EU data protection authorities, **the UK Information Commissioner's Office, or ICO, or the Swiss Federal Data Protection and Information Commissioner, or FDPIC,** while we continue to build our business practices to ensure that all transfers of personal data to us from the European Economic Area, including the EU, United Kingdom and Switzerland, are conducted in compliance with all applicable regulatory obligations, the guidance of data protection authorities and evolving best practices. We may find it necessary to establish systems to maintain personal data originating from the EU in the European Economic Area, which may involve substantial expense and may cause us to need to divert resources from other aspects of our business, all of which may adversely affect our business. Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end- customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could harm on our operations, financial performance, and business. Evolving and changing definitions of personal data and personal information, within the European Union, the United States, and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our products, we may need to expend resources in order to change our business operations, data practices, or the manner in which our products operate. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our products. There is the risk that the limits we obtained for our cyber liability insurance may not cover the total loss experienced in the event of a data security incident, including the financial loss, legal costs, and business and reputational harm, particularly if there is an interruption to our systems. Additionally, there is the risk of a data privacy or security incident by an employee, which may expose us to liability. If personal information of our customers or employees is misappropriated, our reputation with our customers and employees may be injured resulting in loss of business and / or morale, and we may incur costs to remediate possible injury to our customers and employees or be required to pay fines or take other action with respect to judicial or regulatory actions arising out of such incidents. Risks Related to Regulatory and Political Environment The regulatory approval process is expensive, time consuming and uncertain. Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA **or similar foreign regulatory authority** will authorize the commercialization of Motiva Implants or our planned products on a timely basis, if at all, **and, Delays or** failure to obtain necessary clearances or approvals would adversely affect our ability to grow our business. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, where regulations differ from country to country. Our products are registered to be sold in 86-94 countries. **In, including** the United States, we have received clearance from the FDA to sell our Intraoperative Sizers and Flora Tissue Expanders, but we are not permitted to market other planned products until we receive the requisite FDA approval or clearance. **See Item 1 "Business"** The two primary types of FDA marketing authorization in the United States applicable to a device are a premarket approval (by filing a PMA) or a premarket notification clearance (by filing a 510 (k) notice). Breast implants are currently classified as Class III Medical Devices requiring an approved PMA for **additional information about** commercial distribution. Certain of our other **the regulatory** products or modifications to those products are currently eligible for 510 (k) clearance or approval of a PMA supplement. We have not received marketing approval for Motiva Implants in the United States. We have received 501 (k) clearance for the Intraoperative Sizers and Flora Tissue Expanders, which are now commercially available in the United States. Obtaining approval for sale of a medical device from the FDA can be a lengthy, expensive and uncertain process. The PMA approval process generally takes from one to three years and the 510 (k) clearance process usually takes from three to twelve months, although each could take longer. Prior to receiving approval to commercialize any of our planned products in the United States or abroad, we may be required to demonstrate with substantial evidence from preclinical and well- controlled clinical studies, and to the satisfaction of the FDA or other regulatory authorities abroad, that such planned products are safe and effective for their intended uses. We may not successfully complete required clinical trials, or they may yield results which are different than anticipated **or that**. Results

from preclinical studies and clinical studies can be interpreted in different ways. **Additionally, Even even** if we believe the preclinical or clinical data for our planned products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our planned products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications. Regulatory **clearance or approval from the FDA or foreign regulatory authorities** is not guaranteed, and the approval process is expensive and may take several years. **The, particularly where a PMA is required approval process in the United States generally takes from one to three years and the 510 (k) clearance process in the United States usually takes from three to twelve months, although each could take longer. For example, we initiated a modular PMA submission process with the FDA for approval of our Motiva Implants in the United States in 2021 and received FDA approval for our Motiva Implants in the United States in September 2024.** The FDA **and other regulatory authorities** also ~~has~~ **have** substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on **the jurisdiction**, the planned product, the indication that the planned product is designed to address and the regulations applicable to any particular planned product. The FDA can delay, limit or deny approval of a planned product for many reasons, including, but not limited to, the following: ~~→~~ a planned product or one or more of its features may not be deemed safe or effective; ~~→~~ FDA officials may not find the data from preclinical studies and clinical studies sufficient; ~~→~~ the FDA might not approve our manufacturing or our third- party supplier' s processes or facilities; or ~~→~~ the FDA may change its approval policies or adopt new regulations. In addition, the FDA **or other regulatory authority** may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. **The In the United States, the** FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission and approval of a PMA for us to market and sell those products. Any change in the ~~FDA' s~~ approval policies or new or amended regulations governing the clearance and approval processes could increase the costs of obtaining approval / clearance of a product or result in delays in, or failure to receive or maintain clearance or approval for our products. **Moreover, clearance or approval by** the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more international regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. An international regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain international regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and, even if we file, we may not receive necessary approvals to commercialize our products in any market. ~~If Motiva Implants, or our future~~ products, fail to demonstrate safety and efficacy in further clinical studies that may be required for U.S. approval, or do not gain regulatory approval, our business and results of operations will be harmed. ~~If~~ **If** Motiva Implants or any planned products fail to demonstrate safety and effectiveness in preclinical and clinical studies, if there is a change in the ~~FDA' s~~ approval policies or new or amended regulations governing the clearance and approval process for our products, or if our products do not gain regulatory approval or clearance, our business and results of operations will be harmed. Once commercialized, modifications to our marketed products may require new 510 (k) clearances or approval of PMA supplements, or equivalent steps in other countries, or may require us to cease marketing or recall the modified products until certification, clearances or regulatory approvals are obtained. Modifications to any of our products once they are commercialized ~~may from time to time~~ **may from time to time** require new regulatory approvals or clearances, including 510 (k) clearances or approval of PMA supplements, or **may** require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not affect safety or efficacy and does not represent a major change in its intended use, so that no new clearance or approval is necessary. However, the FDA can review a manufacturer' s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval of a PMA supplement is required. We may make modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and / or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions. **For example, if a manufacturer determines that a modification to a PMA approved device could affect its safety or effectiveness or would constitute a major change in its intended use, then the manufacturer must file for a new PMA or approval of a PMA supplement.** Where we determine that modifications to our products require a new PMA approval **or approval of a PMA supplement**, we may not be able to obtain those additional approvals for the modifications or additional indications in a timely manner, or at all. Obtaining new approvals can be a time- consuming process, and delays in obtaining required future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. For those products sold in the EEA, we must notify our EU ~~notified~~ **Notified body Body** if significant changes are made to the products or if there are substantial changes to our quality ~~assurance~~ **management** systems affecting those products. Obtaining ~~certification~~ **CE Certificates of Conformity for medical devices** can be a time- consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Even if we receive regulatory approval for a planned product, we will be subject to ongoing regulatory obligations and continued regulatory review, ~~which~~. **Compliance with ongoing regulatory obligations and**

continued regulatory review may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements. When a regulatory approval is obtained, the approved product and its manufacturer are subject to continual review by the FDA or non- U. S. regulatory authorities. Our regulatory approval for Motiva Implants, as well as any regulatory approval that we receive for future modifications to Motiva Implants or for any planned products may be subject to limitations on the indicated uses for which the product may be marketed. Future approvals may contain requirements for potentially costly post- marketing follow- up studies to monitor the safety and effectiveness of the approved product in real-world post- market use. **For example, in connection with FDA approval of our Motiva Implants, we are required to monitor the clinical trial patients for our IDE clinical trial for up to ten years, create a patient registry or large post approval study, and / or other studies, and implement training programs for physicians.** In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event quarterly reporting, device tracking, device retrieval studies, storage, advertising, promotion and recordkeeping for our products. **If actions, including the issuance of a warning letter, injunction, seizure, civil fine, or criminal penalties, constitute promotion of an untitled letter-off-label use, it could request that we modify our training a warning letter, injunction, seizure, civil fine, or criminal penalties promotional materials or subject us to regulatory or enforcement actions.** It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off- label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. **In that event, our reputation could be damaged and adoption of the products could be impaired.** In addition, the off- label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management' s attention, result in substantial damage awards against us, and **harm our reputation**. We are also required to comply with regulations regarding the manufacture of Motiva Implants, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must inspect these manufacturing facilities and determine that they are in compliance with FDA good manufacturing practice requirements as set forth in the Quality System Regulation, or QSR, before the products can be approved. These facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the QSR and associated regulations. Failure to comply with FDA and other applicable U. S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following: • Warning Letters; • civil or criminal penalties and fines; • injunctions; • suspension or withdrawal of regulatory approval; • suspension of any ongoing clinical studies; • voluntary or mandatory product recalls and publicity requirements; • refusal to accept or approve applications for marketing approval of new devices or supplements to approved applications filed by us; • restrictions on operations, including costly new manufacturing requirements; or • seizure or detention of our products or import bans. Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. Our products are subject to medical device reporting regulations, which require us to report to the FDA any information that reasonably suggests one of our products may have caused or contributed to a death or serious injury, or one of our products malfunctioned and, if the malfunction were to recur, this device or a similar device that we market would be likely to cause or contribute to a death or serious injury. Our obligation to report under the medical device reporting regulations is triggered on the date on which we become aware of information that reasonably suggests a reportable adverse event occurred. 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, it is an adverse event that is unexpected or if the product characteristic that caused the adverse event is removed in time from our products. If we fail to comply with our medical device reporting obligations, the FDA could issue warning letters or untitled letters, take administrative actions, commence criminal prosecution, impose civil monetary penalties, demand or initiate a product recall, seize our products, or delay the clearance of our future products. 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 clearances or 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, which may harm our reputation and have a material adverse effect on our business. We are subject to extensive and dynamic medical device regulation, and oversight in the United States and other countries. If we fail to obtain or maintain necessary regulatory approvals for our products, or if approvals or clearances for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations. Our products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by various regulatory agencies and governing bodies. Under the US Food, Drug and Cosmetic Act (FDCA), medical devices must receive FDA clearance or approval or an exemption from such clearance or approval before they can be commercially marketed in the U. S. Additionally, such devices are subject to wide- ranging regulations including, among other things: product design, development, manufacture and release; laboratory and clinical testing, labeling, packaging, storage, and distribution; product safety and effectiveness; record- keeping; product promotion and advertising; post-marketing surveillance; post- market approval studies, where applicable; and import and export rules. In the EU, we are required to comply with applicable medical device directives (including the **EU MDR Medical Devices Directive and the European Medical Device Regulation**) and obtain CE Mark certification in order to market medical devices. **Breast implants intended for aesthetic purposes fall under Annex XVI (List of groups of products without an intended medical purpose) of the EU**

MDR and are also required to obtain CE Mark certification under the EU MDR in order to be placed on the EU market

. In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. The FDA or other regulators could delay, limit, or deny clearance or approval of a device for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our devices and any accessories are substantially equivalent to a legally marketed predicate device or safe or effective for their proposed intended uses; • disagreement of the FDA with the design or implementation of any clinical trials or the interpretation of data from preclinical studies or clinical trials; • serious and unexpected adverse device effects experienced by participants in our clinical trials; • insufficiency of the data from preclinical studies or clinical trials to support clearance or approval; • our inability to demonstrate that the clinical and other benefits of the device outweigh the risks; • failure of our manufacturing process or facilities to meet applicable requirements; and • the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval. Many countries require that product approvals be renewed or recertified on a regular basis, generally every four to five years. The renewal or recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where renewal or recertification applications are required, they may need to be renewed and / or approved in order to continue selling our products in those countries. There can be no assurance that we will receive the required approvals for new products or modifications to existing products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post- market study requirements. The **EU European Union regulatory bodies finalized a new Medical Device Regulation (MDR) in 2017, which replaced the existing directives and provided three years for transition and compliance. After a one-year delay, the MDR became effective on May 26, 2021. The MDR changes several aspects of the existing previous regulatory framework and imposes additional requirements regarding , such as updating among others, device design and development, preclinical and clinical data requirements and introducing new ones, such as Unique Device Identification premarket conformity assessment and post- market surveillance , or UDI vigilance, and market surveillance . We and , along with the Notified Bodies , may who will oversee compliance to the new MDR face uncertainties as the MDR is continues to be rolled out and enforced by the European Commission and EEA Competent Authorities . The time required to obtain a , creating risks in several areas, including the CE Marking process and data transparency, Certificate of Conformity from a Notified Body in the upcoming years EU is lengthy and may be unpredictable. On average, the time- to- certification under the EU MDR for all device categories ranges between 13 and 18 months .** Additionally, the U. K.' s withdrawal from the EU and the end of the mutual recognition and related trade facilitating effects for medical devices between the EU and Switzerland in May 2021 have added certain costs and complexities to the shipment and sales of our products in those countries. Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances or approvals, seizures or recalls of products, physician advisories or other field actions, operating restrictions and / or criminal prosecution. We may also initiate field actions as a result of a failure to strictly comply with our internal quality policies. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances or approvals, seizures or recalls of products, physician advisories or other field actions, or the withdrawal of product approval or clearance by regulatory authorities could have a material adverse effect on our business, financial condition or results of operations. Our products, such as Motiva Implants, may in the future be subject to product recalls that could harm our reputation, business and financial results. Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, design defects or labeling inadequacies affecting a medical device could lead to a government- mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the agency within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving Motiva Implants or other planned devices in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations. The medical technology industry is complex and intensely regulated at the federal, state, and local levels and government authorities may determine that we have failed to comply with applicable laws or regulations. As a company which manufactures and distributes medical devices and technologies, we are subject to numerous regional, national and local laws and regulations. There are significant costs involved in complying with these laws and regulations. Moreover, if we are found to have violated any applicable laws or regulations, we could be subject to civil and / or criminal damages, fines, sanctions or penalties, including exclusion from participation in governmental healthcare programs. We may also be required to change our method of operations. These consequences could be the result of current conduct or even conduct that occurred a number of years ago. We also could incur significant costs merely if we become the subject of an investigation or legal proceeding alleging a violation of these laws and regulations. We cannot predict whether any government authority will determine that we are not operating in accordance with law, or whether the laws will change in the future and impact our business. Under some circumstances, government investigations can also be initiated by private individuals under whistleblower provisions which may be incentivized by the possibility for private recoveries. Responding to inquiries and enforcement activities can be costly and disruptive to our business operations, even when the allegations are without merit. We also may be subject to other financial sanctions or be required to modify our operations. Any of these actions could have a material adverse

effect on our business, financial condition and results of operations. **If we obtain approval for our products..... us, and harm our reputation.** Our relationship with customers, **patients** and third party payors will be subject to applicable anti-kickback, fraud and abuse, and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, damages, reputational harm and diminished profits and future earnings. Our ~~future~~ arrangements with third-party payors, **patients** and health care providers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or the financial relationships and engagement we enter into to market, sell, promote and distribute our products ~~for which we obtain clearance~~ in the U. S. Efforts to ensure that our business arrangements with these third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. 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, and the curtailment or restructuring of our operations. The requirements and restrictions under these broadly applicable laws and regulations are described in the section on Fraud and Abuse Laws in Item 1 -, **“Business”**. Health care reform measures could hinder or prevent our planned products’ commercial success. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. 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 or approval for, manufacture, market or distribute our products. **Actions by the FDA For- or example-other governmental agencies applicable to our business may be adversely affected by several significant administrative law cases decided by the U. S. Supreme Court in 2024, including most notably, Loper Bright Enterprises v. Raimondo, which overruled the Supreme Court's previous ruling that courts defer to reasonable agency interpretations of statutes that are silent or ambiguous on a particular topic. The ruling requires courts to exercise their independent judgment when deciding whether an agency has acted within its statutory authority, and that courts may not defer to an agency interpretation solely because a statute is ambiguous. This decision and other administrative law cases may result in additional legal challenges to regulations and guidance issued by federal regulatory agencies, including the FDA, that we have relied on and intend to rely on in the future. Any such challenges, if successful, could have a material impact on our business.** In January of 2024, FDA issued a final rule to replace the QSR with the adoption **addition to potential** of ISO 13485. We cannot determine what effect ~~changes in to regulations, statutes, and agency guidance as a result of legal challenges interpretation or policies, these decisions when and if promulgated, enacted or adopted may have on~~ **result in increased regulatory uncertainty and delays in and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations in the future.** **Further** Such changes could, ~~in~~ 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. In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the health care system in ways that could affect our future revenue and future profitability and the future revenue and future profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that could result in significant changes to the health care system, some of which are intended to contain or reduce the costs of medical products and services. **With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify For- or revise laws impacting example, one of the most significant health care reform measures in decades, system or the requirements and policies of the FDA and the other regulatory agencies with jurisdiction over Patient Protection and Affordable Care Act, or our products** PPACA, was enacted in 2010 **the United States**. The **impending uncertainty could present** PPACA contains a number of provisions, including those governing enrollment in federal health care programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government health care programs and will result in the development of new programs. There have been judicial and Congressional challenges to certain aspects of the PPACA. Furthermore, the Tax Cuts and Jobs Act passed in December of 2017 included a provision repealing the PPACA’s individual mandate penalty, the tax-based shared responsibility payment on certain individuals who fail to maintain qualifying health coverage for ~~or potential opportunities~~ all or part of a year. Congress may consider other legislation to repeal or replace elements of the PPACA on a provision-by-provision basis. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we **navigate** cannot predict how future federal or state legislative or administrative changes relating to health care reform will affect our business. In addition, other ~~the continued commercialization~~ legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among **Motiva Implants in other-- the United States** things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$ 1. 2 trillion for the years 2013 through 2021, which triggered the legislation’s automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, starting in 2013. Sequestration is

currently set at 2 % and will increase to 2.25 % for the first half of fiscal year 2030, to 3 % for the second half of fiscal year 2030, and to 4 % for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. We cannot predict the impact that ongoing health care reform will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and / or state level in the United States, and as to the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and / or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for **our Motiva Implants or the other type of current or planned** products we intend to commercialize in the United States (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers of health care services to contain or reduce costs of health care may adversely affect: **•** our ability to set a price that we believe is fair for our products; **•** our ability to generate revenue and achieve or maintain profitability; and **•** the availability of capital. The coverage and reimbursement status of newly- approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue. Market acceptance and sales of any one or more of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third- party payers, such as private health insurers and health maintenance organizations, decide which products they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any of our products or product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop. The pricing, coverage and reimbursement of our product candidates must be adequate to support our commercial infrastructure. Our per- patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. However, sales of any product depend, in part, on the extent to which such product will be covered by third- party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third- party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan- by- plan basis. One third- party payor' s decision to cover a product does not ensure that other payors will also provide coverage for the product. As a result, we do not have assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Further, third- party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical products and product candidates. Adoption of price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit or delay sales of any of our future products. A decision by a third- party payor not to cover a product could reduce patient demand for any of our products. ~~The political situation in the United States can affect the ability of our company to conduct business in certain areas or countries if new trade conditions are imposed or enforced by the U. S. government. There could be negative consequences to our company' s revenue if the U. S. government unexpectedly changes its trade policies towards determined geographies or countries. These policy changes can include such things as trade barriers, which serve to limit or prevent international trade. The U. S. government may request additional funds or tariffs in exchange for the right to export items into the country. Tariffs or quotas may be used to protect domestic producers from foreign competition. Changes may include the modification or withdrawal of free trade agreements already in place. This also can have a large effect on the profits of our company because it either cuts revenues as a result of a tax on imports / exports or restricts the amount of revenues that can be earned. The global economic instability caused by the ongoing military conflicts in Ukraine and Israel may adversely affect our business in Europe and the Middle East. The conflicts in Ukraine and Israel have resulted in worldwide geopolitical and macroeconomic uncertainty and have caused, and will likely continue to cause, disruption and instability in affected markets. It is not possible at this time to predict the ultimate consequences of the conflicts or the responses of governments or others to the conflicts, which could include, among other things, additional sanctions, greater regional instability or expansion of the conflict, embargoes, geopolitical shifts, litigation, and impacts on macroeconomic conditions, commodities, currency exchange rates, supply chains, and financial markets, which could adversely impact our business and results of operations.~~ Risks Related to Taxation Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non- realization of expected benefits. **A- We have subsidiaries in multiple countries. From time to time, tax authority authorities may disagree with tax positions that we have taken. If we are unable to successfully resolve such disagreements, which we could experience result in increased tax liabilities. For example, the U. S. Internal Revenue Service or another foreign tax authority could challenge the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies. A tax authority may, as has occurred recently in Brazil, take the position that certain material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might, as we have in Brazil, contest such assessment. Contesting such an assessment may can be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could materially increase our anticipated effective tax rate, where applicable. In addition, we may be subject to additional tax liabilities, which could materially and adversely affect our business, financial condition and results of operations. The application, interpretation and enforcement of value- added tax, or VAT, and other taxes and related regulations applicable to medical device companies is complex and evolving. We are a multinational organization faced with increasingly complex tax issues in many jurisdictions, and changes in tax laws or their application to the**

operation of our business could adversely impact our operating results and our business. We conduct operations in multiple jurisdictions, and we are subject to certain taxes, including income, sales and use, employment, value added and other taxes, in the United States and other jurisdictions in which we do business. A change in the tax laws in the jurisdictions in which we do business, including an increase in tax rates or an adverse change in the treatment of an item of income or expense, possibly with retroactive effect, could result in a material increase in the amount of taxes we incur. Our determination of our tax liability is subject to review by applicable U. S. and foreign tax authorities. Any adverse outcome of such a review could harm our operating results and financial condition. The determination of our worldwide provision for income taxes and other tax liabilities requires significant judgment and, in the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is complex and uncertain. Moreover, as a multinational business, we have subsidiaries that engage in many intercompany transactions in a variety of tax jurisdictions where the ultimate tax determination is complex and uncertain. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies, which could impact our financial position and operating results. Historically, we have allocated some of our employees' and contractors' time across multiple business entities in the international jurisdictions in which we operate. If it were determined that we had misclassified our employees' or contractors' employment status or certain of our expenditures under local laws, we may be subjected to penalties or be required to pay withholding taxes, extend employee benefits, provide compensation for unpaid overtime, or otherwise incur substantially greater expenses with respect to such employees and contractors. Any of the foregoing circumstances could have a material adverse impact on our operating results and financial condition. In addition, the European Union Economic and Financial Affairs Council has in recent years released a list of non-cooperative jurisdictions for tax purposes. The stated aim of the list is to promote good governance worldwide in order to maximize efforts to promote fair tax competition and address harmful tax practices. In February 2023, Costa Rica was added to this list, which now includes 16 jurisdictions. According to the European Union Economic and Financial Affairs Council, Costa Rica was added to the list because it has not fulfilled a commitment to abolish or amend harmful aspects of its foreign source income exemption regime. In October 2023, the EU Council announced that three jurisdictions have been removed from the list of non-cooperative tax jurisdiction, one of which was Costa Rica. This follows the reforms made to the Costa Rica's Income Tax Law, amending aspects of the foreign-source income exemption regime. The reforms include a clarification to the scope of the territoriality principle and introduction of a new taxation regime for foreign-source passive income. We are periodically reviewed and audited by tax authorities with respect to income and non-income taxes. Tax authorities may disagree with certain positions we have taken, and we may have exposure to additional income and non-income tax liabilities which could have an adverse effect on our operating results and financial condition. Such authorities could impose additional taxes, interest and penalties, claim that various withholding requirements apply to us or our subsidiaries or assert that benefits of tax treaties are not available to us or our subsidiaries. In addition, our future effective tax rates could be favorably or unfavorably affected by changes in tax rates, changes in the valuation of our deferred tax assets or liabilities, the effectiveness of our tax planning strategies, or changes in tax laws or their interpretation. Such changes could have an adverse impact on our financial condition. As a result of these and other factors, the ultimate amount of tax obligations owed may differ from the amounts recorded in our financial statements and any such difference may harm our operating results in future periods in which we change our estimates of our tax obligations or in which the ultimate tax outcome is determined. Our ability to use net operating losses to offset future taxable income and certain other tax attributes may be subject to certain limitations. Federal and California laws impose restrictions on the utilization of net operating loss carryforwards and research and development credit carryforwards in the event of a change in ownership of the Company, which constitutes an "ownership change" as defined by Internal Revenue Code Sections 382 and 383. Generally, an ownership change occurs if the percentage of the value of the shares that are owned by one or more direct or indirect "five percent shareholders" increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period. If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes. We have not experienced an ownership change in the past that would materially impact the availability of its net operating losses and tax credits. Nevertheless, future changes in our share ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 and 383 limitations. We have not completed a Section 382 and 383 analysis to determine if an ownership change has occurred. Until such analysis is completed, we cannot be sure that the full amount of the existing net operating loss carryforwards will be available to us, even if we do generate taxable income before their expiration. In addition, under the newly enacted U. S. federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. U. S. holders of our common shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company. A non-U. S. corporation will be classified as a passive foreign investment company, or PFIC, for U. S. federal income tax purposes, in any taxable year in which either (1) at least 75% of its gross income is passive income; or (2) at least 50% of the average quarterly value of its total gross assets is attributable to assets that produce "passive income" or are held for the production of passive income. Based on the project composition of our income and valuation of our assets, we do not believe we were a PFIC in 2024 and 2023 and 2022, and we do not expect to become one in the future. However, because our PFIC status is subject to a number of uncertainties, neither we nor our tax advisors can provide any assurances regarding our PFIC status. If we are a PFIC for any taxable year during which a U. S. holder holds our common shares, the U. S. holder may be subject to adverse tax consequences. U. S. investors should consult their advisors regarding the application of these rules and the availability of any potential elections. If a United States person is treated as owning at least 10% of our common shares, such holder may be subject to adverse U. S. federal income tax consequences. If a United States person is treated as owning (directly, indirectly, or constructively) at least 10% of the value or voting power of our ordinary shares, such person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). We may become a controlled foreign

corporation. In addition, because our group includes one or more U. S. subsidiaries, certain of our non- U. S. subsidiaries could be treated as controlled foreign corporations (regardless of whether or not we are treated as a controlled foreign corporation). A U. S. shareholder of a controlled foreign corporation may be required to report annually and include in its U. S. taxable income its pro rata share of “ Subpart F income, ” “ global intangible low- taxed income, ” and investments in U. S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a U. S. shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U. S. shareholder that is a U. S. corporation. Failure to comply with these reporting obligations may subject a U. S. shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder’ s U. S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether we or any of our non- U. S. subsidiaries is treated as a controlled foreign corporation or whether any investor is treated as a U. S. shareholder with respect to any such controlled foreign corporation or furnish to any U. S. shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A U. S. investor should consult its advisors regarding the potential application of these rules to an investment in our common shares. Discontinuation of preferential tax treatments we currently enjoy or other unfavorable changes in tax law could result in additional compliance obligations and costs. Discontinuation of preferential tax treatments we currently enjoy or other unfavorable changes in tax law could result in additional compliance obligations and costs. We are currently the beneficiary of a tax holiday in Costa Rica pursuant to which we are subject to a tax at a 0 % rate. The tax holiday is effective through December 31, 2030, and it may be extended if certain additional requirements are satisfied. However, there can be no assurance that we will continue to qualify for or receive such favorable tax treatment after the expiration date. If we fail to maintain such favorable tax treatment, we may be subject to tax in Costa Rica at a significantly higher rate.

Risks Related to Ownership of Our Securities Our share price may be volatile, and purchasers of our securities could incur substantial losses. The price at which our common shares trade may be volatile. The securities markets in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Additionally, the lack of an active market may impair the value of our common shares, or your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. Although our common shares are listed on Nasdaq, if we fail to satisfy the continued listing standards, we could be delisted, which would negatively impact the price of our common shares. The market price for our shares may be influenced by many factors, including the following:

- our ability to successfully commercialize, and realize revenues from sales of, Motiva Implants;
- the success of competitive products or technologies;
- results of clinical studies of Motiva Implants or planned products or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing processes or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in- license additional products or planned products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost- effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of health care payment systems;
- negative shifts in the economy **effecting-affecting** the number of aesthetic breast procedures;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding our common shares, other comparable companies or our industry generally;
- trading volume of our common shares;
- sales of our common shares by us or our shareholders;
- short selling activities;
- the impact of pandemics, epidemics or other public health crises;
- general economic, industry and market conditions; and
- the other risks described in this “ Risk Factors ” section. These broad market and industry factors may harm the market price of our common shares, regardless of our operating performance. In the past, following periods of volatility in the market, securities class- action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’ s attention and resources, which could adversely affect our business, financial condition, results of operations and growth prospects. We identified a material weakness in our internal control over financial reporting as of December 31, 2023, **and 2022**, ~~and 2021~~, and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our consolidated financial statements. If we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U. S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Prior to the completion of our IPO, we were a private company with limited accounting and compliance personnel and other resources to address our internal control over financial reporting. On December 31, 2021, it was determined that our primary user access controls (i. e. provisioning, de- provisioning, and quarterly user access review) to ensure appropriate segregation of duties that would adequately restrict user and privileged access to the financially relevant systems and data to appropriate Company

personnel were not operating effectively. These user access control deficiencies resulted in a lack of segregation of duties with respect to certain user roles. Automated process- level controls and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency. During the fourth quarter of 2023, we completed our testing of the operating effectiveness of the implemented controls and found them to be effective. As a result, we have concluded the material weakness identified as of December 31, 2021 has been remediated as of December 31, 2023. It was determined that as of December 31, 2023, our primary change management controls for direct database changes were not designed and implemented effectively for specific localities. Other Information Technology General Controls, automated process- level controls, and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency. We have made significant progress remediating change management controls as of December 31, 2023. We improved policies and procedures and designed and documented more effective change management monitoring controls, through the use of systematic audit logging, that addresses the relevant risks in order to remediate the identified material weakness. As a result, we have concluded the material weakness persists and will not be considered identified as of December 31, 2023 has been remediated until the applicable controls operate for a sufficient period of time, and management has as concluded, through testing, that the control objective is achieved, and the controls are operating effectively. We expect that the remediation of December 31, this material weakness will be completed during 2024. We also expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. If additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, it may materially adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner and impact investor confidence in our Company. The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. The identification and remediation of additional material weaknesses in the future, could adversely affect our ability to report financial information, including our filing of quarterly or annual reports with the SEC on a timely and accurate basis and prohibit us from producing timely and accurate consolidated financial statements, which may adversely affect our share price and impact investor confidence in our Company and we may be unable to maintain compliance with Nasdaq listing requirements. Risks Related to Being a British Virgin Islands Company Rights of shareholders under British Virgin Islands law differ from those under U. S. law, and, accordingly, you may have fewer protections as a shareholder. Our corporate affairs are governed by our amended and restated memorandum and articles of association, the BVI Act, and the common law of the British Virgin Islands. The rights of shareholders to take legal action against our directors, actions by minority shareholders and the fiduciary responsibilities of our directors under British Virgin Islands law are to a large extent governed by the common law of the British Virgin Islands and by the BVI Act. The common law of the British Virgin Islands is derived in part from comparatively limited judicial precedent in the British Virgin Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the British Virgin Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under British Virgin Islands law are not as clearly established as they would be under statutes or judicial precedents in some jurisdictions in the United States. In particular, the British Virgin Islands has a less developed body of securities laws as compared to the United States, and some states (such as Delaware) have more fully developed and judicially interpreted bodies of corporate law. As a result of the foregoing, holders of our ordinary shares may have more difficulty in protecting their interests through actions against our management, directors or major shareholders than they would as shareholders of a U. S. company. British Virgin Islands companies may not be able to initiate shareholder derivative actions, thereby depriving shareholders of one avenue to protect their interests. British Virgin Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States. The circumstances in which any such action may be brought, and the procedures and defenses that may be available in respect of any such action, may result in the rights of shareholders of a British Virgin Islands company being more limited than those of shareholders of a company organized in the United States. Accordingly, shareholders may have fewer alternatives available to them if they believe that corporate wrongdoing has occurred. The British Virgin Islands courts are also unlikely to recognize or enforce judgments of courts in the United States based on certain liability provisions of U. S. securities law, or to impose liabilities based on certain liability provisions of the U. S. securities laws that are penal in nature, in original actions brought in the British Virgin Islands. There is no statutory recognition in the British Virgin Islands of judgments obtained in the United States, although the courts of the British Virgin Islands will generally recognize and enforce the non- penal judgment of a non- U. S. court of competent jurisdiction without retrial on the merits. This means that even if shareholders were to sue us successfully, they may not be able to recover anything to make up for the losses suffered. British Virgin Islands law differs from the laws in effect in the United States, and U. S. investors may have difficulty enforcing civil liabilities against us, our directors or members of senior management. Under our amended and restated memorandum and articles of association, we may indemnify and hold our directors harmless against all claims and suits brought against them, subject to limited exceptions. Furthermore, to the extent allowed by law, the rights and obligations among or between us, any of our current or former directors, officers and employees and any current or former shareholder will be governed exclusively by the laws of the British Virgin Islands and subject to the jurisdiction of the British Virgin Islands courts, unless those rights or obligations do not relate to or arise out of their capacities as such. Although there is doubt as to whether U. S. courts would enforce these provisions in an action brought in the United States, under U. S. securities laws, these provisions could make judgments obtained outside of the British Virgin Islands more difficult to enforce against our assets in the British Virgin Islands or jurisdictions that would apply British Virgin Islands law. The laws of the British Virgin Islands provide limited protection for

minority shareholders, so minority shareholders will have limited or no recourse if they are dissatisfied with the conduct of our affairs. Under the laws of the British Virgin Islands, there is limited statutory law for the protection of minority shareholders other than the provisions of the BVI Act dealing with shareholder remedies, as summarized under “ Description of Share Capital- Shareholders’ Rights Under British Virgin Islands Law Generally. ” One protection under statutory law is that shareholders may bring an action to enforce the constituent documents of a British Virgin Islands company and are entitled to have the affairs of the Company conducted in accordance with the BVI Act and the amended and restated memorandum and articles of association of the Company. As such, if those who control the Company have disregarded the requirements of the BVI Act or the provisions of our amended and restated memorandum and articles of association, then the courts will likely grant relief. Generally, the areas in which the courts will intervene are the following: (i) an act complained of which is illegal ; (ii) acts that constitute oppression, unfair discrimination or unfair prejudice against the minority where the wrongdoers control the Company ; (iii) acts that infringe on the personal rights of the shareholders, such as the right to vote ; and (iv) acts where we have not complied with provisions requiring approval of a special or extraordinary majority of shareholders, which are more limited than the rights afforded to minority shareholders under the laws of many states in the United States. Provisions in our amended and restated memorandum and articles of association and under British Virgin Islands law could make an acquisition of us more difficult and may prevent attempts by our shareholders to replace or remove our current management. Provisions in our amended and restated memorandum and articles of association may discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which shareholders 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 our common shares, thereby ~~depressing~~ **reducing** the market price of our common shares. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our shareholders to replace current members of our management team. Among others, these provisions include the following: • while we are commencing a phased- in process to declassify our Board of Directors, our Board of Directors is divided into three classes with staggered three- year terms and will not be fully declassified until our 2026 annual meeting of shareholders, which may delay or prevent a change of our management or a change in control; • our Board of Directors has the right to elect directors to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which will prevent shareholders from being able to fill vacancies on our Board of Directors; • our shareholders are not able to act by written consent, and, as a result, a holder, or holders, controlling a majority of our shares are not able to take certain actions other than at annual shareholders’ meetings or special shareholders’ meetings; • our amended and restated memorandum and articles of association do not allow cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates; • our shareholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board of Directors or to propose matters that can be acted upon at a shareholders’ meeting, which may discourage or deter a potential ~~acquirer~~ **acquirer** from conducting a solicitation of proxies to elect the ~~acquirer~~ **acquirer**’ s own slate of directors or otherwise attempting to obtain control of our company; and • our Board of Directors is able to issue, without shareholder approval, preferred shares with voting or other rights or preferences that could impede the success of any attempt to acquire us. Moreover, because we are incorporated in the British Virgin Islands, we are governed by the provisions of BVI Business Companies Act, 2004, as amended, or the BVI Act, which provide for different shareholder rights than a Delaware corporation. See, for example, the risk factor titled “ Rights of shareholders under British Virgin Islands law differ from those under U. S. law, and, accordingly, you may have fewer protections as a shareholder. ” ~~68-62~~