Risk Factors Comparison 2024-12-06 to 2023-12-08 Form: 10-K

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Our business faces significant risks. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. Our business, financial condition and results of operations could be materially adversely affected by any of these risks, and the trading prices of our common stock could decline by virtue of these risks. These risks should be read in conjunction with the other information in this report. Risks Relating to Our Business Current market conditions and recessionary pressures in one or more of our markets could impact our ability to grow our business. Over the last few years in the United States and globally, market and economic conditions have been challenging. The United States and foreign countries have experienced recessionary pressures and face continued concerns about the systemic impacts of adverse economic conditions and geopolitical issues. Any negative impact on economic conditions and international markets, continued volatility or deterioration in the debt and equity capital markets, inflation, deflation or other adverse economic conditions may adversely affect our liquidity and financial condition. It may limit our ability to replace maturing liabilities and to access the capital markets to meet liquidity needs, which could have a material adverse effect on our business. Ongoing uncertain economic and financial market conditions may also adversely affect the financial condition of our customers, suppliers and other business partners. When our customers' financial conditions are adversely affected, customers may reduce their purchases of our products or we may not be able to collect accounts receivable, each of which could have a material adverse impact on our business. Our global business has been negatively affected by local economic conditions, including inflation, increasing labor costs, recession, and currency exchange rate fluctuations, which has adversely affected our cost to manufacture and provide our products and services and revenues generated through sales of such products and services. We cannot guarantee that we will be able to fully absorb any such additional costs or revenue declines in the prices for our products and services. CooperVision and CooperSurgical are encountering consolidation in their customer bases and emergence of more centralized large customer groups and retail chains. Due to this trend, global and regional key account customers now represent a larger proportion or concentration of our business and any disruption to these relationships may have a material adverse impact on our business. Inflation could materially adversely affect our business. Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors that impact our cost structure and revenue. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, ~~the war in Ukraine and other~~ international conflicts, and steps taken by governments and central banks, as well as other stimulus and spending programs, have led to higher inflation, which is likely to lead to an increase in costs and may cause changes in fiscal and monetary policy, including increased interest rates. In a higher inflationary environment, we may be unable to raise the prices of our products and services sufficiently to keep up with the rate of inflation. Our substantial and expanding international operations are subject to uncertainties which could affect our business. A significant portion of our current operations are conducted and located outside the United States, and our growth strategy involves expanding our existing foreign operations and entering into new foreign jurisdictions. We have significant manufacturing and distribution sites in North America, Latin America and Europe. More than half of our net sales for the fiscal years ended October 31, **2024, and** 2023 ~~and 2022~~ , were derived from the sale of products outside the United States. We believe that sales outside the United States will continue to account for a material portion of our total net sales for the foreseeable future. International operations and business expansion plans are subject to numerous additional risks, including the following: • difficulty managing a large organization spread throughout various countries; • fluctuations in currency exchange rates adversely affecting our results; • challenges associated with enforcing intellectual property rights in some foreign countries; • difficulty gaining market share in countries such as China because of regulatory restrictions and customer preferences; THE COOPER COMPANIES, INC. AND SUBSIDIARIES • difficulty growing our sales in emerging markets such as China, India, Russia, Brazil and other developing nations due to, among other things, customer acceptance, undeveloped and / or unfamiliar distribution channels, regulatory restrictions and changes, and business knowledge of these new markets; • foreign earnings being subject to withholding requirements or the imposition of tariffs, exchange controls or other restrictions, including the tariffs enacted by the Chinese government on certain U. S. goods, the scope and duration of which remain uncertain; • challenges in complying with a variety of international legal, compliance and regulatory requirements such as the Foreign Corrupt Practices Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the UK Bribery Act, international data security and privacy laws, EU MDR and EU IVDR ~~,~~ and environmental laws and requirements applicable to our facilities, products or manufacturing processes, including evolving regulations regarding the use of hazardous substances or chemicals in our products ~~,~~ **; • the need to engage third-party agents or intermediaries to act on our behalf in certain countries, including in those countries with a high risk of corruption;** • foreign customers creating longer payment cycles than customers in the United States; • failure to comply with U. S. Department of Commerce and other nations' import- export controls may result in fines and / or penalties; • general economic and political conditions in the countries where we operate having an adverse effect on our operations in those countries or being unfavorable to our growth strategy; • **international conflicts, acts or threats of war or terrorism may lead to significant market and other disruptions, supply chain interruptions, political and social instability, trade disputes or trade barriers, embargoes, changes in consumer or purchase preferences, as well as an increase in cyberattacks and espionage; • challenges in complying with new and evolving international economic and trade sanctions laws and regulations; •** natural disasters, pandemics **and** ~~, war, terrorism,~~ labor disruptions ~~and international conflicts may cause significant economic disruption and political and social instability~~ , **the duration** ~~resulting in decreased demand for our products, adversely affecting~~

~~our manufacturing~~ and ~~distribution capabilities, or causing interruptions in our supply chain~~ **severity of which are highly uncertain and difficult to predict** ; • foreign governments adopting regulations, including those similar to the EU MDR and EU IVDR or take other actions that would have a direct or indirect adverse impact on our business and market opportunities, including but not limited to increased enforcement of potentially conflicting and ambiguous anti- bribery and privacy laws; • challenges enforcing agreements and collecting receivables through some foreign legal systems; and • unforeseen economic or political events in certain countries that may have an impact on our customers' ability or preferences to buy our products. As we continue to expand our business globally, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. However, any of these factors could adversely affect our international operations and, consequently, our business. **Economic** ~~International Conflicts, such as the war between Russia~~ and ~~Ukraine,~~ **trade sanctions** could ~~adversely affect~~ **make it more difficult or costly for us to conduct our operations or achieve** our business **objectives** ~~. On February 24, 2022, Russian military forces launched a military action in Ukraine. The military conflict is ongoing and the length, impact, and outcome is highly unpredictable. It has led and could continue to lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy resources, instability in financial markets, supply chain interruptions, political and social instability, trade disputes or trade barriers, changes in consumer or purchaser preferences, as well as an increase in cyberattacks and espionage. The war has led to significant sanctions programs imposed by the United States, the EU, the UK, Canada, Switzerland, Japan, and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so- called Donetsk People' s Republic, and the so- called Luhansk People' s Republic. In retaliation against new international sanctions and as part of measures to stabilize and support the volatile Russian financial and currency markets, the Russian authorities also imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia, imposed various restrictions on transacting with non-Russian parties, banned exports of various products, and imposed other economic and financial restrictions. The situation continues to evolve and additional sanctions by Russia on the one hand, and by the other countries on the other hand, could adversely affect the global economy, financial markets, energy supply and prices, certain critical materials and metals, supply chains, and global logistics and could adversely affect our business~~ . Our business must be conducted in compliance with applicable economic and trade sanctions laws and regulations, including those administered and enforced by the U. S. Department of Treasury' s Office of Foreign Assets Control, the U. S. Department of State, the U. S. Department of Commerce, the United Nations Security Council, and other relevant governmental authorities. ~~If we~~ **These laws and regulations may restrict or prohibit altogether the sale or supply of certain of our products to certain governments, persons, entities, countries, and territories, including those that** are **the target** ~~found to be in violation~~ of **comprehensive** ~~U. S.~~ sanctions **, unless there are license exceptions that apply** or ~~export control~~ **specific licenses are obtained. A failure to comply with these** laws ~~, it~~ **and regulations** could result in ~~substantial~~ **civil or criminal sanctions, including the imposition of** fines and ~~penalties for us and for individuals working for us. We are actively monitoring~~ the ~~situation in Ukraine and Russia and assessing its impact~~ **denial of export privileges, which could have a material adverse effect** on our business ~~, including our business partners, employees and customers. To date, we have not experienced any material interruptions in our infrastructure, supplies, technology systems, or networks needed to support our operations. The conflict has caused us to modify our operations in Russia and could lead to additional modifications in Russia. We cannot predict the progress or outcome of the war or its impacts in the territories where we operate. The extent and duration of the military action, sanctions, other consequences, such as Russia imposing restrictions on transactions or banning the export of energy products, including natural gas, and the resulting market disruptions could be significant and could potentially have substantial impact on the global economy and our business for an unknown period of time. Any such disruption may also magnify the impact of other risks described in this section~~ . Acquisitions and other strategic transactions that we have made and may make in the future involve numerous risks. We have a history of acquiring businesses and products that have significantly contributed to our growth in recent years. As part of our growth strategy, we intend to continue to consider acquiring complementary technologies, products and businesses and establishing joint ventures or other strategic relationships. Future transactions could result in potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities and an increase in amortization and / or impairments of goodwill and other intangible assets, which could have a material adverse effect upon our business ~~. In fiscal 2022, CooperVision acquired a private Denmark- based ortho- k contact lens distributor. In fiscal 2022, CooperSurgical acquired a private cryopreservation services company and Generate Life Sciences (Generate), a private provider of donor egg and sperm for fertility treatments, fertility cryopreservation services and newborn stem cell storage (cord blood and cord tissue)~~ . Risks we could face with respect to these acquisitions and other strategic transaction include: • failure to successfully obtain the anticipated revenues, margins and earnings benefits; • difficulties in, and expenses related to, the integration of the operations, technologies, information technology and other enterprise resource planning systems, products and personnel of the acquired company and establishment of appropriate accounting controls and reporting procedures, data protection systems and other regulatory compliance procedures, including but not limited to third- party compliance and due diligence; • increased leverage and the risk of lack of access to available financing, including financing for the acquisition or refinancing of debt owed by us on a timely basis and on reasonable terms; • risks of entering markets in which we have no or limited prior experience; • potential loss of employees; • an inability to identify and consummate future acquisitions on favorable terms or at all; • diversion of management' s attention away from other business concerns; • risks of the acquired company' s noncompliance with applicable laws or regulations; • expenses of any undisclosed or potential liabilities, contingent liabilities or indemnification obligations of the acquired company; • expenses, including restructuring expenses, to shut down our own locations or terminate our employees; • application of and compliance with new and unfamiliar regulatory frameworks ~~such as regulation applicable to our newly acquired fertility- related businesses~~ ; • failure to successfully obtain or maintain reimbursements under the third- party payor plans, including but not limited to governmental programs, due to complex reporting and payment obligations; • our

ability to develop satisfactory working arrangements with our strategic partners in joint ventures or other affiliations; • a dilution of earnings per share; and • risks inherent in accounting allocations and the risk that we are required to record significant adjustments to the preliminary fair value of assets acquired and liabilities assumed within the measurement period. We face risks associated with disruption of our manufacturing, distribution and storage operations, including possible failure to develop necessary manufacturing processes, or constrained, idle or excess capacity, which could adversely affect our business. We manufacture a significant portion of the medical device products we sell. Any prolonged disruption in the operations of our existing manufacturing or distribution facilities or our fertility and stem cell storage facilities, whether due to work stoppages, technical or labor difficulties, integration difficulties, destruction of or damage to any facility (as a result of natural disaster, use and storage of hazardous materials or other events), enforcement action by the FDA or other regulatory body if we are found to be in non- compliance with current ~~Good Manufacturing Practices (~~ cGMP ~~)~~ or similar foreign requirements or other reasons, could have a material adverse effect on our business. In addition, materials such as silicone hydrogel require improvements to our manufacturing processes to make them cost- effective. While we have improved our manufacturing capabilities for our silicone hydrogel products, our failure to continue to develop improvements to our manufacturing processes and reduce our cost of goods could significantly impact our ability to compete. Conversely, constrained, excess or idle capacity, which could result from acquisitions, unexpected demand, inaccurate sales forecasting or unexpected manufacturing efficiencies, could significantly impact our profitability, capital investments, customer service levels and near- term financial condition. CooperVision manufactures molded contact lenses, which represent the majority of our contact lens revenues, primarily at our facilities in Costa Rica, Hungary, Puerto Rico, the United Kingdom and the United States, with other smaller facilities also existing in multiple locations around the world. CooperSurgical manufactures the majority of its products in Costa Rica, the United Kingdom and the United States, with other smaller locations also existing in multiple locations around the world. We manufacture certain products at only one manufacturing site for certain markets, and certain of our products are approved for manufacturing only at one site. Further, certain media products have limited storage lives, limiting inventory back- up strategies. If there were any prolonged disruption in the operations of the approved facility, it could take a significant amount of time to obtain required regulatory approvals, validate a second site and replace lost product, which could result in lost customers and thereby reduce sales, profitability and market share. CooperVision distributes products out of Belgium, Hungary, the United Kingdom and the United States and various smaller international distribution sites. CooperSurgical primarily distributes products out of its facilities in the United States and the Netherlands and operates fertility and stem cell storage facilities in the United States, Canada and Australia. Any prolonged disruption in the operations of our existing distribution or storage facilities, whether due to technical or labor difficulties, challenges related to system implementation, destruction of or damage to any facility (as a result of natural disaster, use and storage of hazardous materials or other events) or other reasons, could have a material adverse effect on our business. Cybersecurity threats continue to increase in frequency and sophistication; a successful cybersecurity attack could interrupt or disrupt our information technology systems, or those of our third- party service providers, or cause the loss of confidential or protected data which could disrupt our business, force us to incur excessive costs or cause reputational harm. Security breaches, computer malware and computer hacking attacks have become more prevalent across industries and may occur on our systems or those of our third- party service providers or partners. The size and complexity of our information systems make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. Such attacks are increasing in their frequency, levels of persistence, levels of sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise, especially given increased vulnerability of corporate information technology systems as distributed work environments have become prevalent. In addition to unauthorized access to or acquisition of personal data, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial- of- service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. Like many other companies, we experience attempted cybersecurity actions on a frequent basis, and the frequency of such attempts could increase in the future. While we have **implemented procedures and controls to monitor and mitigate security threats and** invested in the protection of data and information technology, we cannot be assured that our efforts will prevent or quickly identify service interruptions or security breaches. The techniques used by cybercriminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot be assured that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages or breaches in our systems or those of our third- party services providers or partners. Any such interruption or breach of our systems could adversely affect our business operations and / or result in the loss of critical or sensitive confidential information **, including protected health information (PHI),** or intellectual property, and could result in financial, legal, business and reputational harm to us **, which could have a material adverse effect on our financial position, results of operations and cash flows. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information** . We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems **, and we cannot guarantee that applicable insurance will be available to us in the future on economically reasonable terms or at all** . We manage our businesses utilizing multiple complex integrated software and hardware information technology operating systems that are regularly maintained and upgraded; an interruption or disruption to these systems could disrupt our business or force us to incur excessive costs. We utilize multiple complex integrated software and hardware operating systems, including enterprise resource

planning and warehouse management systems, to support our business units and we have a continuous improvement strategy in place to keep our systems and overarching technology stable and in line with business needs and growth. Regular upgrades of our computer hardware and software revisions are typical and expected. We employ controlled change management methodologies to plan, test and execute all such system upgrades and improvements, and we believe that we assign adequate staffing and other resources to projects to ensure successful implementation. However, we cannot be assured that our systems will meet our future business needs or that upgrades will operate as designed. We cannot be assured that there will not be associated excessive costs or disruptions in portions of our business in the course of our maintenance, support and / or upgrade of these systems. We are in the midst of a multiyear process of implementing new enterprise resource planning (ERP) systems at CooperVision and CooperSurgical. Implementing a new ERP system is not only costly but complex and difficult. Implementing a new ERP system can negatively affect not only financial accounting and reporting processes but also external commercial activities such as order receipt and product delivery. We cannot be assured that we will successfully implement our new ERP system or that we will avoid these and other negative impacts from our implementation efforts. **If any of such systems or programs were to experience service interruptions, fail or create erroneous information in our hardware or software network infrastructure, possible consequences include our loss of communication links, inability to track sales and interruption of other operational or financial processes, which in turn could adversely affect our financial results, stock price and reputation. We identified a material weakness in our internal control over financial reporting related to an ineffective information technology (IT) general control for the U. S. operations within the CooperSurgical segment which, if not remediated appropriately or timely, could affect our ability to record, process and report financial information accurately and prepare financial statements within required time periods and could subject us to litigation or investigations, negatively affect investor confidence and adversely impact our stock price. Internal controls related to the operation of technology systems are critical to maintaining adequate internal control over financial reporting. As disclosed in Part II, Item 9A, during fiscal 2024, management concluded our internal control over financial reporting was not effective as of October 31, 2024 due to a material weakness in IT general controls for the CooperSurgical operations in the U. S. primarily related to the implementation and maintenance of certain enterprise resource planning systems during fiscal 2024. The material weakness resulted from not having a sufficient complement of its personnel, inadequate training of personnel and ineffective assessment of the risks related to change management, user control monitoring and segregation of duties in the affected IT environment. Manual controls that rely on system- generated data or reports from the affected IT environment or process level automated controls in the affected IT environment were ineffective because they could have been adversely impacted. In response to the material weakness, management, with the oversight of the Audit Committee, has begun to implement steps to remediate the material weakness. If we are unable to remediate the material weakness, or are otherwise unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process and report financial information accurately, and to prepare financial statements within required time periods, could be adversely affected, which could subject us to reputational harm, legal claims or proceedings, regulatory investigations and enforcement actions, significant costs from remedial actions, additional management resources, and payment of legal and other expenses, negatively affect investor confidence in our financial statement and adversely impact our stock price.** Pricing pressure from our competitors, customers and changes in third- party coverage and reimbursement may adversely affect demand for our products and negatively impact our operating results. Competition in our industry has increased as a result of new market entrants, new technologies and as more established companies have intensified competitive pricing pressure. As a result of these competitive forces, we believe there will continue to be pricing pressure in the future. Because our CooperSurgical products are generally purchased by hospitals and ~~surgical~~ **surgery** centers, OB / GYN medical offices and fertility clinics, and billed to various third- party payors, changes in the purchasing behavior of such customers or the amount such payors are willing to reimburse our customers for procedures using our products, including as a result of healthcare reform initiatives, could create additional pricing pressure on us. In addition to these competitive forces, we continue to see pricing pressure as our customers introduce new pricing structures into their contracts and agreements, including fixed price formulas, capitated pricing and structured pricing intended to contain healthcare costs. Such trends may adversely affect demand for our products and may drive down the prices we are able to charge for our products, both of which would negatively affect our operating results. We rely on independent suppliers in our supply chain for raw materials, packaging materials and components, mechanical equipment and some finished goods; we could experience inventory shortages if any of these suppliers encounter a manufacturing or distribution disruption. Our businesses utilize various chemicals, packaging materials, components, parts and raw materials which are generally available from more than one source. However, in certain instances we acquire components and materials from sole or primary suppliers to make our silicone hydrogel contact lens, certain medical devices and IVF products. We also source mechanical equipment and in certain instances finished goods from OEM suppliers. Supply of these goods, items and materials is protected by contractual agreements, availability of alternative suppliers and / or safety stocks. However, if current suppliers fail to supply sufficient goods, items or materials to us on a timely basis, or at all for any reason, we could experience inventory shortages and disruption in our supply of products. For example, among other situations, some of the primary material used to make our silicone hydrogel contact lens products, including MyDay, Biofinity, Avaira and clariti, are supplied by few or sole suppliers, and the failure of a key or sole supplier to timely supply sufficient items and materials necessary for the manufacture of our silicone hydrogel contact lenses could in turn disrupt our supply of those lenses to the market, which would have a material adverse effect on our business. Our supply chain and our cost of goods also may be negatively impacted by unanticipated price increases due to factors such as inflation, including wage inflation, or to supply restrictions beyond our control or the control of our suppliers ~~. Our results of operations have been adversely affected, and our results of operations, cash flow and financial condition could be materially adversely affected in the future, by the global COVID- 19 pandemic and related~~

~~economic disruptions. The COVID- 19 pandemic has negatively impacted business and healthcare activity globally and has created significant volatility, uncertainty and economic disruption within the markets in which we operate. The pandemic has adversely affected and is likely to further adversely affect nearly all aspects of our business and markets, including our sales, operations, cash flow and workforce and the operations of our customers, suppliers, vendors and business partners. The extent to which the COVID- 19 pandemic and related economic disruptions impact our business, results of operations, cash flow and financial condition will depend on future developments, which are highly uncertain, difficult to predict and largely outside of our control. Even after the COVID- 19 pandemic has subsided, we may continue to experience materially adverse effects on our business~~ . If we fail to protect our intellectual property adequately, our business could suffer. We consider our intellectual property rights, including patents, trade secrets, trademarks and licensing agreements, to be an integral component of our business. We attempt to protect our intellectual property rights through a combination of patent, trademark, copyright and trade secret laws, as well as licensing agreements and third- party nondisclosure and assignment agreements. Our failure to obtain or maintain adequate protection of our intellectual property rights for any reason could have a material adverse effect on our business. We also may seek to enforce our intellectual property rights on others through litigation. Our claims, even if meritorious, may be found invalid or inapplicable to a party we believe infringes or has misappropriated our intellectual property rights. In addition, litigation can: • be expensive and time consuming to prosecute or defend; • result in a finding that we do not have certain intellectual property rights or that such rights lack sufficient scope or strength; • divert management' s attention and resources; or • require us to license our intellectual property. We have applied for patent protection in the United States, the United Kingdom and other foreign jurisdictions relating to certain existing and proposed processes and products. We cannot be assured that any of our patent applications will be approved. Patent applications in the United States, the United Kingdom and other foreign jurisdictions are maintained in secrecy for a period of time, which may last until patents are issued, and since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we will be the first creator of inventions covered by any patent application we make or the first to file patent applications on such inventions. The patents we own could be challenged, invalidated or circumvented by others and may not be of sufficient scope or strength to provide us with any meaningful protection or commercial advantage. We also cannot assure that we will have adequate resources to enforce our patents. Both CooperVision and CooperSurgical also rely on proprietary technology that is unpatented. It is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology. To protect our trade secrets and other proprietary information, our employees, consultants, advisors and collaborators enter into confidentiality agreements and assignment agreements, which generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, we cannot be assured that these confidentiality agreements will provide meaningful protection for our trade secrets, know- how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know- how or other proprietary information. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. We rely on trademarks to establish a market identity for our products. To maintain the value of our trademarks, we might have to file lawsuits against third parties to prevent them from using trademarks confusingly similar to or dilutive of our registered or unregistered trademarks. We also might not be successful in obtaining registrations for our pending or future trademark applications and might have to defend our registered trademark and pending applications against challenge by third parties. Enforcing or defending our registered and unregistered trademarks might result in significant litigation costs and damages, including the inability to continue using certain trademarks. The laws of foreign countries in which we do business or contemplate doing business in the future may not recognize intellectual property rights or protect them to the same extent as do the laws of the United States. Adverse determinations in a judicial or administrative proceeding could prevent us from manufacturing and selling our products or prevent us from stopping others from manufacturing and selling competing products, and thereby have a material adverse effect on our business. Our products or processes could be subject to claims of infringement of the intellectual property of others. Our competitors in both the United States and foreign countries, some of which have substantially greater resources and have made substantial investments in competing technologies, as well as other third parties, may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our existing and planned products. In the contact lens industry, CooperVision, its competitors and other third parties hold patents covering contact lens designs, materials, processes and business methods. Claims that our products, business methods or processes infringe upon the proprietary rights of others often are not asserted until after commencement of commercial sales of products incorporating our technology. Significant litigation regarding intellectual property rights exists in our industries. For example, CooperVision in the past faced significant patent litigation over its silicone hydrogel contact lens products. Third parties have made, and may make in the future, claims of infringement against us or our contract manufacturers in connection with the use of our technology. Any claims, even those without merit, could: • be expensive and time consuming to defend; • cause us to cease making, licensing or selling products that incorporate the challenged intellectual property; • require us to redesign or re- engineer our products, if feasible; • require us to enter into royalty or licensing agreements in order to obtain the right to use a necessary product, component or process. We cannot be certain of the outcome of any litigation. A successful claim of infringement against us or our contract manufacturers in connection with the use of our technology, in particular if we are unable to manufacture or sell any of our planned products in any major market, could adversely affect our business. Any royalty or licensing agreement, if required, may not be available to us on acceptable terms or at all. Our failure to obtain the necessary licenses or other rights could prevent the sale, manufacture, or distribution of some of our products and, therefore, could have a material adverse effect on our business. We could experience losses from product liability claims or legal claims relating to our service offerings, including such claims and other losses resulting from sales of counterfeit and other infringing products. We face an inherent risk of exposure to product liability claims in the event that the use of our products results in personal injury. We also face the risk

that defects in the design or manufacture of our products or sales of counterfeit or other infringing products might necessitate a product recall and other actions by manufacturers, distributors or retailers in order to safeguard the health of consumers and protect the integrity of the subject brand. Additionally, we face the inherent risk of exposure to legal claims, including negligence, relating to our provision of certain service offerings, including the accuracy and quality of our genomic services, fertility cryopreservation, fertility donor gamete supply, and stem cell storage services. These risks may be heightened due to our direct- to- consumer marketing efforts for some of our products and services (e. g., stem cell storage and Paragard IUDs). Consumers may halt or delay purchases of a product or service that is the subject of a claim or recall or has been counterfeited. We handle some risk with third- party carrier policies that are subject to deductibles and limitations. These insurance policies may become more expensive (or not be available) for new risks we may assume when we acquire new businesses. We cannot be assured that we will not experience material losses due to product liability claims or recalls, legal claims relating to our service offerings, or a decline in sales resulting from sales of counterfeit or other infringing products, in the future. If our products **or services** are not accepted by the market, we will not be able to sustain or expand our business. Certain of our proposed products **or services** have not yet been clinically tested or commercially introduced, and some of our existing products **or services** are marketed and sold on the basis of potential future medical or therapeutic value (assuming technology advances), and we cannot be sure that any of them will achieve market acceptance or generate revenues or operating profits. The development of a market for our products **or services** may be influenced by many factors, some of which are out of our control, including: • acceptance of our products **or services** by eye care ~~and~~ **or other** health care practitioners; • the cost competitiveness of our products **and services** ; • consumer reluctance to try and use a new product **or service** ; • regulatory and legislative requirements; • adequate coverage and reimbursement by third- party payors; • lack of scientific advancements to validate the medical value of certain products **or services** , such as stored cord blood or cord tissue (or scientific advancements in other medical approaches that reduce or eliminate the value of such products **or services**); and • the earlier release of competitive products **or services** , such as new silicone hydrogel products or contraceptive technologies, into the market by our competitors; and the emergence of newer and more competitive products **or services** . We operate in the highly competitive health care industry, and we cannot be assured that we will be able to compete successfully. Each of our businesses operates within a highly competitive environment. In our soft contact lens business, CooperVision faces intense competition from competitors' products, in particular silicone hydrogel contact lenses, and may face increasing competition as other new products enter the market. Our largest competitors in the contact lens business, Johnson & Johnson Vision Care, Inc., Alcon Inc. and Bausch Health Companies Inc. may have substantially greater financial resources, larger research and development budgets, larger sales forces, greater market penetration and / or larger manufacturing volumes than CooperVision. They offer competitive products and differentiated materials, plus a variety of other eye care products including lens care products and ophthalmic pharmaceuticals, which may give them a competitive advantage in marketing their lenses. The market for contact lenses is intensely competitive and is characterized by declining sales volumes for older product lines and growing demand for silicone hydrogel- based products. Our ability to respond to these competitive pressures will depend on our ability to decrease our costs and maintain gross margins and operating results and to introduce new products successfully, on a timely basis in the Americas, EMEA and Asia Pacific, and to achieve manufacturing efficiencies and sufficient manufacturing capacity and capabilities for such products. Any significant decrease in our costs per lens will depend, in part, on our ability to increase sales volume and production capabilities and our ability to secure adequate supply of materials used in production at reasonable costs. Our failure to respond to competitive pressures in a timely manner could have a material adverse effect on our business, financial condition and results of operations. To a lesser extent, CooperVision also competes with manufacturers of eyeglasses and providers of other forms of vision correction including ophthalmic surgery. We cannot be assured that we will not encounter increased competition in the future, for example with increased product entries from Asia Pacific contact lens manufacturers, or that our competitors' newer contact lens products will not successfully erode CooperVision' s contact lens business, which could have a material adverse effect on our business. The contact lens industry also continues to evolve with respect to the introduction of new distribution and fulfillment models and service technologies which may conflict with CooperVision' s strategy or interfere with its customers' relationships and loyalty. For example, more contact lenses are being fulfilled directly to the consumer by manufacturers and wholesalers via online platforms, telemedicine is gaining popularity and more vision correction prescriptions are being provided through online refractive exams rather than in office by an eye care practitioner. CooperVision' s failure to adapt to the threats posed by these new and emerging distribution models and Internet driven services may have a material adverse impact on our business. CooperSurgical focuses on selected segments of the family and women' s health care market with a diversified portfolio of products and services including fertility products and services, medical devices, cryostorage (such as cord blood and cord tissue storage) and contraception. Competitive factors in these segments in which CooperSurgical competes include technological and scientific advances, product quality and availability, price, customer service including response time and effective communication of product information to physicians, consumers, fertility clinics and hospitals. Competition in the medical device industry is dynamic and involves the search for technological and therapeutic innovations. CooperSurgical competes with a number of manufacturers and service providers in its women' s family health care market areas. Some of these competitors have substantially greater financial and personnel resources and sell a broader range of products, which may give them an advantage in marketing competitive products. In addition, some of CooperSurgical' s markets, such as genomics, contraception and cord blood and cord tissue storage, are characterized by rapid technological advancement. We face the risk that demand for our products will not grow or will decline if our competitors are more successful than us at innovating in these and other areas. There is also risk that emerging technologies or technology advancements could reduce the medical value of certain of our products and services, such as cord blood and cord tissue storage, which could adversely affect our business. In recent years, CooperSurgical has also expanded direct- to- consumer products and services, which requires implementing new competitive strategies and increases the importance of customer service and consumer reputation as competitive factors. New

medical and technological developments may reduce the need for our products. Technological developments in the vision, fertility and women' s health, may limit demand for our products and services. For example, corneal refractive surgical procedures such as Lasik surgery and the development of new pharmaceutical products may decrease the demand for our optical products. If these new advances provide a practical alternative to traditional vision correction, the demand for contact lenses and eyeglasses may materially decrease. We cannot be assured that medical advances and technological developments will not have a material adverse effect on our business. Product innovations are important in the industry in which we operate, and we face the risk of product obsolescence if we are unable to develop new products or gain regulatory approvals or certifications or if our competitors introduce new products. Product innovations are important in the contact lens market in which CooperVision competes and in the areas of the health care industry in which CooperSurgical competes. CooperVision, both internally and externally with third parties, invests in new product development, including the development of new silicone hydrogel- based contact lenses. While much of CooperVision' s research and development activities are performed internally, it also uses external research and development investment in collaborations and joint development with third parties. CooperSurgical has historically purchased, leveraged or licensed the technology developments of others. CooperSurgical also has invested in expanding the internal research and development function with the goal of organic growth and to complement our acquisitions strategy. Research and development time commitments, higher feasibility risk with longer term projects, greater dependence on, and reduced control over, third- party deliverables, the cost of obtaining necessary regulatory approval or certification and other costs related to product innovations can be substantial. We cannot be assured that we will successfully obtain necessary regulatory approvals, certifications or clearances for our new products or that our new products will successfully compete in the marketplace and, as a result, justify the expense involved in their development and regulatory approval or certification. In addition, our competitors may have developed or may in the future develop new products or technologies. Failure to develop new product offerings and technological changes and to offer products that provide performance that is at least comparable to competing products could have a material adverse effect on our business. We face risks related to environmental, social and governance matters. We and our facilities are subject to a broad range of U. S federal, state, local and foreign environmental laws and requirements, including those governing discharges to the air and water, the handling or disposal of solid and hazardous substances and wastes, remediation of contamination associated with the release of hazardous substances at our facilities and offsite disposal locations and occupational safety and health. We have made, and will continue to make, expenditures to comply with such laws and requirements. Future events, such as changes in existing laws and regulations, or the enforcement thereof, or the discovery of contamination at our facilities, may give rise to additional compliance or remediation costs that could have a material adverse effect on our business. Such laws and requirements are constantly changing, are different in every jurisdiction and can impose substantial fines and sanctions for violations. As a manufacturer of various products, we are exposed to some risk of claims with respect to environmental matters, and we cannot be assured that material costs or liabilities will not be incurred in connection with any such claims. We continue to evaluate the necessary steps for compliance with regulations as they are enacted. These regulations include, for example, regulations enacted in the EU such as the Registration, Evaluation, Authorization and Restriction of Chemical Substances, which requires the registration of and regulates use of certain chemicals, the Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive, which regulates the use of certain hazardous substances in certain products our CooperSurgical division manufactures. These and similar legislation that has been or is in the process of being enacted in Japan, China and various states of the United States may require us to re- design certain products to ensure compliance with the applicable laws and regulations. In addition, new disclosure standards and rules related to ~~environmental, social and corporate governance (~~ESG ~~)~~ matters have been adopted and may continue to be introduced in various states and other jurisdiction. For example, the European Union Corporate Sustainability Reporting Directive (CSRD) became effective in 2023 and applies to both EU and non- EU entities. In October 2023, California adopted new carbon and climate- related reporting requirements for large public and private companies doing business in the state. Further, the SEC **adopted a** ~~is expected to finalize~~ --- **final** ~~a~~ **rule on the Enhancement and Standardization of** ~~climate~~ **Climate** ~~change~~ **- Related** ~~disclosure~~ **Disclosures** ~~proposal~~ in ~~2023~~ **2024** . International ESG disclosure standards have also been produced (and further standards will be produced) under the auspices of the International Sustainability Standards Board (ISSB), which some countries (such as the UK) have indicated they may incorporate into ESG disclosure standards required of certain companies. As the nature, scope and complexity of ESG reporting, diligence and disclosure requirements expand, significant effort and expenses could be required to comply with the evolving requirements. As our disclosure obligations increase, third parties may make claims or bring litigation relating to those disclosures which may be costly. Environmental, social and corporate governance ~~(ESG)~~ issues, including those related to climate change and sustainability, may have an adverse effect on our business and damage our reputation. There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us. Customers, consumers, investors and other stakeholders are increasingly focusing on environmental issues, including climate change, energy and water use, plastic waste and other sustainability concerns. Concern over climate change or plastics and packaging materials, in particular, may result in new or increased legal and regulatory requirements to reduce or mitigate impacts to the environment. Changing customer and consumer preferences or increased regulatory requirements may result in increased demands or requirements regarding plastics and packaging materials, including single- use and non- recyclable plastic products

and packaging, other components of our products and their environmental impact on sustainability, or increased customer and consumer concerns or perceptions (whether accurate or inaccurate) regarding the effects of substances present in certain of our products. Complying with these demands or requirements could cause us to incur additional manufacturing, operating or product development costs. If we do not adapt to or comply with new regulations, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our Company, and customers and consumers may choose to stop purchasing our products, which could have a material adverse effect on our reputation and business. If we do not retain our key personnel and attract and retain other highly skilled employees, our business could suffer. If we fail to recruit, develop and retain the necessary personnel, our business and our ability to obtain new customers, develop new products and provide acceptable levels of customer service could suffer. The success of our business is heavily dependent on the leadership of our key management personnel. Our success also depends on our ability to recruit, develop and retain and motivate highly skilled sales, marketing, manufacturing engineering and scientific personnel. Competition for these persons in our industry is intense, and we may not be able to successfully recruit, train or retain qualified personnel. We are experiencing increasing challenges in building and retaining our workforce in certain markets, where pressure from inflation and competition have exacerbated turnover and retention trends ~~continuing from the COVID- 19 pandemic~~ . Labor shortages and competition for qualified personnel could cause disruptions in our business operations. Provisions of our governing documents and Delaware law may have anti- takeover effects. Certain provisions of our Second Restated Certificate of Incorporation and Amended and Restated By- Laws may inhibit changes in control of the Company not approved by our Board of Directors. These provisions include advance notice requirements for stockholder proposals and nominations. We also have the protections of Section 203 of the Delaware General Corporation Law, which could have anti- takeover effects. Risks Relating to Government Regulation of Manufacture and Sale of Our Products and Services. Legislative or regulatory reforms in the United States, Europe or other countries may make it more difficult and costly for us to obtain regulatory clearances, approvals or certifications for our products or to manufacture, market or distribute our products after clearance or approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of drugs and medical devices. In addition, the FDA may change its premarket clearance and approval policies for drugs and medical devices, 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. For example, over the last several years, the FDA has proposed reforms to its 510 (k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510 (k) clearance process for their products. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping. In addition to traditional regulatory controls on drugs and medical devices, our business could be affected by emerging laws or regulations limiting our ability to offer certain of our products and services. For example, in the United States, the reversal by the U. S. Supreme Court of Roe v. Wade has raised concerns in the fertility industry that more restrictive laws could limit access to various reproductive services. New and emerging laws may be interpreted to limit access to contraceptive technologies or cryostorage services, which could adversely affect certain aspects of CooperSurgical' s business. In addition, the EU landscape concerning medical devices (including IVDs) has recently evolved **and may be subject to further developments in 2025** . A new set of two EU regulations have been adopted on April 5, 2017. On May 26, 2021, the EU MDR became applicable and replaced previous directives and established transitional provisions. The EU IVDR became applicable on May 26, 2022. However, ~~on October 14, 2021,~~ the European ~~Commission proposed~~ **institutions adopted subsequent regulations amending the EU IVDR for** a **gradual** ~~" progressive "~~ roll- out of the EU IVDR to prevent ~~disruption~~ **disruptions** in the supply of IVDs ~~. The European Parliament and Council adopted the proposed regulation on December 15, 2021~~ . The EU IVDR fully applies since May 26, 2022, but there is a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation. Both regulations have been adopted to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices (including IVDs) and ensure a high level of safety and health while supporting innovation. These modifications may have an effect on the way we intend to develop our business in the EU and EEA. For example, as a result of the transition towards the new regimes, notified body review times have lengthened, and product introductions could be delayed or canceled. Additionally, only a few notified bodies have been designated for EU IVDR certification, which could adversely affect our ability to grow our business. Following the end of the " Brexit " transitional period, from January 1, 2021, the ~~Medicines and Healthcare products Regulatory Agency (~~ MHRA ~~)~~ became the UK' s independent regulatory agency for medical devices. Post- Brexit, amendments have been made to the existing UK medical devices legislation which require medical devices to be registered with the MHRA before being placed on the Great Britain market. Manufacturers based outside of the UK need to appoint a UK Responsible Person to register devices with the MHRA. **On January 9** ~~Following a government consultation on changes to the UK' s medical device regulations~~ , **2024,** the **MHRA** ~~response to which was~~ published **a roadmap setting out** ~~on June 26, 2022, it~~ **its** ~~is anticipated that~~ **plans and timelines for towards** the **reform** ~~core aspects~~ of the **regulatory framework for** ~~future regime will now apply from July 1, 2025 so that~~ medical devices ~~placed on the market~~ in **the** ~~Great Britain (England, Scotland, and Wales) will require a~~ UK ~~Conformity Assessment (UKCA) mark~~ . ~~However,~~ **Regulations implementing core elements of** the ~~MHRA~~ **new framework are intended**

to be in place by 2025. Pending such reform of the UK regulatory framework, the government has ~~recently~~ confirmed that ~~, subject to certain conditions,~~ general medical devices compliant with the EU ~~medical devices directive (EU~~ MDD ~~) or EU active implantable medical devices directive (EU AIMDD)~~ with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of certificate or June 30, 2028. ~~IVDs~~ **Medical devices, including custom- made devices, compliant** with ~~valid certification~~ **the EU MDR** can ~~continue to~~ be placed on the **Great Britain** market **up** until ~~the earlier of certificate expiry or~~ June 30, 2030 ~~. In advance of the new regime, the government also intends to introduce specific legislation on post- market surveillance, with new provisions expected to apply from mid- 2024. However, UKCA marking alone will not be recognized in the EU~~ . The rules for placing medical devices on the **market in** Northern Ireland ~~market will~~ **, which is part of the UK,** differ from those in Great Britain **(England, Scotland and Wales) and continue to be based on EU law** . These ~~modifications~~ **developments, or the perception that any related developments could occur, have had and** may **continue to** have ~~an~~ **a material adverse** effect on ~~the way we intend to conduct~~ **global economic conditions and financial markets, and** our business ~~in~~ **may be impacted and** ~~these~~ -- **the** ~~countries~~ **demand for our products could be depressed** . Our ~~medical device~~ products are subject to reporting requirements and recalls, even after receiving regulatory clearance, approval or certification, which could harm our reputation and business. After a **drug or** device is placed on the market, numerous regulatory requirements apply, including the FDA' s **cGMP and** QSR regulations, which require manufacturers to follow, among other things, design, testing, production, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; and ~~medical device~~ **adverse event** reporting regulations that require us to report to FDA or similar governmental bodies in other countries if our products may have caused or contributed to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA and similar governmental bodies in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. ~~Medical device manufacturers~~ **Manufacturers** , such as CooperVision and CooperSurgical, may, under their own initiative, recall a product if a reasonable possibility of serious injury or any material deficiency in a ~~device~~ **product** is found, or withdraw a product ~~to improve device performance or~~ for other reasons. The FDA requires that certain **medical device** corrections or removals, including recalls, be reported to the FDA within ten working days of initiating the correction or removal. Recalls of any of our products may divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall could harm our reputation with customers and consumers which could reduce the sales of our products. In addition, the FDA or other foreign governmental agencies may implement enforcement actions in connection with a recall which could impair our product offerings and be harmful to our business and financial results. If our manufacturing operations fail to comply with applicable regulations, our manufacturing could be delayed or disrupted, our products could be subject to recall, and sales and profitability could suffer. Our manufacturing operations and processes are required to comply with numerous federal, state and foreign regulatory requirements, including the FDA' s cGMP **regulations for drugs and QSR** for medical devices ~~, known as the QSR regulations~~ , which govern the procedures related to the design, testing, production processes, controls, quality assurance, labeling, packaging, storage, importing, exporting and shipping of our products. We also are subject to state requirements and licenses applicable to manufacturers of **drugs and** medical devices. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic unscheduled inspections by governmental agencies, including the FDA, state authorities and comparable agencies (as well as audits by notified bodies) in other countries. Failure to comply with **cGMP,** QSR ~~requirements~~ and other applicable domestic or international regulatory requirements or to respond to any adverse inspectional observations or product safety issues could result in disruption of our operations and manufacturing delays in addition to, among other things, warning letters, significant fines, injunctions, suspension of approvals, seizures, recalls or import holds of products, operating restrictions and criminal prosecutions. As a result, any failure to comply with applicable requirements could adversely affect our product sales and profitability. On ~~February 23~~ **January 31** , ~~2022~~ **2024** , the FDA issued a ~~proposed~~ **final** rule to amend the QSR regulations to align more closely with the International Organization for Standardization standards. ~~This proposal has not yet been finalized or adopted.~~ Accordingly, ~~it is unclear the extent to which~~ this ~~or any other proposals, if adopted,~~ could impose additional or different regulatory requirements on CooperVision and CooperSurgical that could increase the costs of compliance or otherwise create competition that may negatively affect our business. The manufacture of ~~pharmaceutical therapeutics~~ **drug-device combination products** , such as Paragard, is complex and requires significant expertise and capital investment. We and our contract manufacturers must comply with **applicable** cGMP **, QSR and similar foreign** regulations and guidelines. Manufacturers of pharmaceutical therapeutics often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other ~~contaminations~~ **contamination** are discovered in our ~~therapeutics~~ **drug products** or in the manufacturing facilities in which our **drug products** ~~therapeutics, if approved,~~ are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of any of our ~~therapeutics~~ **drug products** will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to **continue marketing our drug products** ~~provide any therapeutic candidates to patients in clinical trials~~ would be jeopardized ~~. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely~~ . Any adverse developments affecting ~~clinical or commercial~~ manufacturing of our ~~therapeutics~~ **products** may result in shipment delays, inventory shortages, lot

failures, ~~therapeutic~~ **product** withdrawals or recalls, or other interruptions in the supply of our **products** ~~therapeutics or therapeutic candidates~~. We may also have to take inventory write- offs and incur other charges and expenses for **products** ~~therapeutics or therapeutic candidates~~ that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the ~~development and~~ commercialization **and marketing** of any of our **products** ~~therapeutics or therapeutic candidates~~ and could have a material adverse effect on our business. Our failure to comply with regulatory requirements or to receive regulatory clearance, approval or certification for our products or operations could adversely affect our business. Our products and operations are subject to rigorous regulation by the FDA, and numerous other federal, state and foreign governmental authorities. In the United States, the FDA regulates virtually all aspects of medical device and pharmaceutical design, development, testing, manufacture, safety, labeling (including, for example, unique device identifier regulations), storage, recordkeeping, reporting, marketing, promotion, advertising and distribution, as well as product import and export. Our failure to comply with FDA regulations could lead to the imposition of administrative or judicial sanctions, including injunctions, fines, warning letters, suspensions or the loss of regulatory **clearances or** approvals, product recalls, termination of distribution or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible. Our medical devices and pharmaceutical products require clearance or approval by the FDA before they can be commercially distributed in the United States and may require similar approvals by foreign regulatory agencies before distribution in foreign jurisdictions. Medical devices and drug products may only be marketed for the indications for which they are approved or cleared. The process of obtaining, renewing and maintaining regulatory clearances and approvals to market **product** ~~a medical device~~, particularly from the FDA, can be costly and time consuming. We cannot be assured that such clearances and approvals will be granted on a timely basis, if at all, and significant delays in the introduction of any new products or product enhancements may occur, which could adversely affect our competitive position and results of operations. In addition, the FDA and authorities in foreign jurisdictions may change their policies, adopt additional regulations or revise existing regulations, each of which could prevent or delay premarket approval or clearance of our products, increase the cost of compliance, impose additional regulatory requirements on us, or otherwise impact our ability to market our currently approved or cleared products. Modifications and enhancements to medical devices ~~also~~ require a new FDA clearance or approval if they could significantly affect its safety or effectiveness or would constitute a major change in its intended use, design or manufacture. The FDA requires every medical device manufacturer to make this determination in the first instance, but the FDA may review any manufacturer' s decision. We have made modifications and enhancements to our medical devices that we do not believe require a new clearance or ~~application~~ **approval**, but we cannot confirm that the FDA will agree with our decisions. If the FDA requires us to seek clearance or approval for a modification of a previously cleared product for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties, which could have a material adverse effect on our financial results and competitive position. We also cannot assure that we will be successful in obtaining clearances or approvals for our modifications, if required. Our efforts to promote some of our products and services via direct- to- consumer marketing initiatives may subject us to additional scrutiny by the FDA, FTC or other agencies. For example, we promote ~~Paragard~~ **PARAGARD** and cord blood and cord tissue storage directly to end consumers. Regulatory agencies may **further** scrutinize our practices with respect to effective communication of risk information, benefits or claims with respect to such products. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products and product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results may be adversely affected. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability, which would adversely affect our business. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Subject to transitional provisions and in order to sell our products in the EU, our products must respectively comply with general safety and performance requirements of the EU MDR and the EU IVDR. Compliance with these requirements is a prerequisite to be able to affix the European Conformity (CE) mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in the Annexes to the EU MDR and EU IVDR including that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low- risk medical devices (Class I) or general IVDs (Class A), where the manufacturer can self- assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects of a medical device), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product' s technical dossiers and the manufacturer' s quality system (notified body must presume that quality systems which implement the relevant harmonized standards — ISO

13485: 2016 for Quality Management Systems — conform to these requirements). If satisfied that the relevant product conforms to the general safety and performance requirements, the notified body issues ~~an EU~~ **a CE** certificate, which the manufacturer uses as a basis for its ~~own~~ declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to remain in compliance with applicable EU laws, directives or regulations, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EU and EEA. In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and / or sub- contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties. The EU regulatory landscape concerning medical devices (including IVDs) ~~has recently evolved~~ **is continuously evolving** and the new requirements may have a significant effect on the way we conduct our business in the EU and the EEA. Following Brexit, the UK regulatory landscape concerning medical devices (including IVDs) is evolving and may have a significant effect on the way we conduct our business in the UK. See Risk Factors – " Legislative or regulatory reforms in the United States or Europe may make it more difficult and costly for us to obtain regulatory clearances, approvals or certifications for our products or to manufacture, market or distribute our products after clearance or approval is obtained ". Development and marketing of our products are subject to strict governmental regulation by foreign regulatory agencies, and failure to receive, or delay in receiving, foreign qualifications or certifications could have a material adverse effect on our business. In many of the foreign countries in which we market our products, we are subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, the reporting of certain payments to health care practitioners in certain markets (for example, the French anti- gift legislation), duties and tax requirements. Many of the regulations applicable to our devices and products in such countries are similar to those of the FDA. The advertising and promotion of medical devices is subject to some general principles set forth in the EU legislation. Directive 2006 / 114 / EC concerning misleading and comparative advertising and Directive 2005 / 29 / EC on unfair commercial practices, while not specific to the advertising of medical devices, apply to the advertising thereof and contain general rules, for example, requiring that advertisements be evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals. In many countries, the national health or social security organizations require our products to be qualified before they can be marketed with the benefit of reimbursement eligibility. To date, we have not experienced difficulty in complying with these regulations. However, our failure to receive, or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on our business, financial condition and results of operations. Increased regulatory scrutiny of genetic testing may adversely affect our business through increased costs and risks associated with gaining marketing approvals or certifications and potential ~~decreased~~ **impact on** demand for our genetic testing services **. In the United States, in vitro diagnostic devices (IVDs) are a type of medical device that can be used in the diagnosis or detection of diseases or other conditions. The FDA considers laboratory developed tests (LDTs) to be a subset of IVDs that are designed, manufactured, and used within a single laboratory. Similar tests are also known as In- House Tests (IH- Tests) in the EU and LDTs have historically been subject to enforcement discretion by the FDA and were not previously regulated under the 98 / 79EC in- vitro diagnostic directive (IVDD) of the EU. On May 6, 2024, the FDA published a final rule on the regulation LDTs, making explicit that LDTs are medical devices under the FDCA. In addition, the FDA is finalizing a policy under which the FDA will provide greater oversight of IVDs offered as LDTs through a phaseout of its general enforcement discretion approach over the course of four years, as well as targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories** . We offer certain genetic testing services to help identify the likelihood of pregnancy as well as identify possible disorders or diseases of a child prior to birth **,** ~~. Regulatory~~ and **we** ~~legislative proposals addressing oversight of genetic testing~~ have ~~been introduced~~ **historically marketed these tests as LDTs** in the United States **. As a result** , **our tests may now be subject to the FDA' s enforcement of its medical device regulations and the applicable FDCA provisions, subject to the four year phase- out of enforcement discretion beginning in May of 2025. Compliance with the new requirements may require additional analytical or clinical studies or other actions in order to continue marketing our tests during the phase- out period, which could increase costs and expenses or otherwise negatively affect our business. The FDA LDT regulation is currently subject to legislative challenges which may result in less stringent requirements or a decrease in FDA enforcement of LDT requirements. Therefore, the costs to comply with the FDA LDT regulation and its impact on our business is difficult to predict. Similarly, in the EU, the regulatory landscape has evolved to include the definition of** ~~and~~ **an** ~~we~~ **IH- Test as is an IVD that is developed and produced by a laboratory on a non- industrial scale and is provided to health institutions in accordance with Article 5 of the EU IVDR. Under such circumstances, many IH- Tests may continue to be exempt from regulation indefinitely or until 2030 in circumstances where commercially available CE marked options exist. Our genetic tests may be subject to the full application of the EU IVDR with respect to some or all of our existing, as well as future, tests if our tests do not qualify for an IH- Test exemption. We may be required to expend additional time and resources to comply with the requirements of the EU IVDR, resulting in additional expenses for offering our current and any future tests as well as possibly delaying or suspending development or commercialization of such tests. We** expect that new proposals ~~will be introduced from time to time both in the United States and in foreign countries in the future. Although the FDA has statutory authority to assure that medical devices, including IVDs, are safe and effective for~~ **or legislative** ~~their intended uses, the FDA~~

~~has historically exercised its enforcement discretion and not enforced applicable provisions of the FDCA and regulations with respect to laboratory-developed tests (LDTs). The FDA defines LDTs as a type of in vitro diagnostic test that is designed, manufactured, and used within a single laboratory. We believe our tests fall within the definition of an LDT. As a result, we believe our tests are not currently subject to the FDA's enforcement of its medical device regulations and the applicable FDCA provisions. However, if there are~~ changes ~~in the FDA's policy, or if the FDA disagrees that our marketed tests are LDTs or that we are marketing our tests outside the scope of the FDA's current policy of enforcement discretion, we may become subject to extensive regulatory requirements and may be required to stop selling our existing tests or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. This could significantly increase the costs and expenses of conducting, or otherwise harm, our business. Legislative proposals addressing the FDA's oversight of LDTs have been introduced by Congress in the past and new legislative proposals~~ may be introduced from time to time **both** in the ~~future~~ **U**. **S** ~~The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's ability to enforce its medical device regulations with respect to certain LDTs is difficult to predict at this time. If the FDA ultimately begins to enforce its medical device requirements with respect to LDTs, our genetic tests may be subject to additional regulatory requirements imposed by the FDA, the nature and extent of which would depend upon applicable final guidance or regulation by the FDA or instruction by Congress. For example, as part of the Spring 2023 Unified Agenda, the FDA published a proposed rule to the Office of Management and Budget to amend~~ -- **and in foreign countries** ~~FDA regulations to make explicit that LDTs are devices under the FDCA. If the FDA imposes significant changes to the regulation of LDTs it could reduce our revenue or increase our costs and adversely affect our business~~. Any new FDA enforcement policies affecting LDTs or ~~new legislation,~~ regulations such as the EU IVDR ~~regulation may~~ **is likely to** result in increased regulatory ~~burdens~~ **burden** on our ability to continue marketing our genetic products and to develop and introduce new products in the future, which could ~~reduce our revenue or increase our costs and~~ adversely affect our business ~~. In addition, changes in the way the EU regulates LDTs could result in additional expenses for offering our current and any future tests or possibly delay or suspend development or commercialization of such tests. In the EU, the regulatory landscape has recently evolved and the general safety and performance requirements set out in the EU Good Manufacturing Practice guidelines are also applicable to devices manufactured and used only within health institutions. Manufacturers of such devices are required to demonstrate conformity with the general safety and performance requirements through performance evaluations and the manufacturer's quality management system framework. The EU IVDR provides that, with the exception of the relevant general safety and performance requirements, the requirements imposed by the EU IVDR on in vitro diagnostic medical devices do not generally apply to devices manufactured and used only within health institutions established in the EU, provided that certain conditions are met. Under the EU IVDR, health institutions may manufacture, modify and use medical devices within such institutions, thereby addressing the specific needs of target patient groups on a non- industrial scale. Under such circumstances, where the LDTs are manufactured and used strictly within health institutions (which may include hospitals, laboratories, public health institutions that support the healthcare system and / or address patient needs but do not treat or care for patients directly), LDTs would continue to be exempt from regulation. However, compared to the EU IVDD, the exemptions for LDTs will, overall, be narrowed, as even in relation to LDTs, health institutions — among others — are required to provide information upon request on the use of such devices to their competent authority and each health institution will have to draw up a declaration which it will make publicly available. If these conditions are not met and / or diagnostic tests are manufactured and used only within health institutions but " on an industrial scale, " such tests will qualify as in vitro diagnostic medical devices with the full applicability of the EU IVDR. LDTs regulated by the EU IVDR will be subject to conformity assessments and inspections by the relevant competent authority, who will also review the declarations and statements made by the health institutions in relation to their LDTs. If our tests do not qualify for an exemption, we may be subject to the full application of the EU IVDR with respect to some or all of our existing, as well as future, tests, and we would be required to expend additional time and resources to complying with the requirements of the EU IVDR~~. If we fail to comply with applicable federal, state, local and foreign laboratory licensing requirements, we could lose the ability to perform our genetic tests or experience disruptions to our business. We are subject to the ~~Clinical Laboratory Improvement Amendments of 1988 (~~CLIA ~~)~~, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratories must be certified under CLIA and ISO 15189 in order for us to perform testing on human specimens. In addition, our proprietary tests must also be recognized as part of our accredited programs under CLIA so that we can offer them in our laboratory. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The law also requires us to maintain a state laboratory license to conduct testing in that state. In addition, we are subject to the UK Human Fertilization & Embryology Association (HFEA) regulating IVF. Our laboratories are located in Japan, the United Kingdom and United States, and we must maintain the requisite licenses in each jurisdiction. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, **or** a state or foreign license or accreditation, could have a material and adverse effect on our diagnostic testing business, operating results and financial condition. **Three federal agencies are responsible for administering the CLIA program in the United States: the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the FDA.** The CMS ~~also~~ **in particular** has the authority to impose a wide range of sanctions, including revocation of ~~the~~ CLIA certification along with a bar on the ownership or operation of a CLIA- certified laboratory by any owners or operators of the deficient laboratory. If we were to lose our CLIA certification or required state or foreign licensure, we would not be able to operate our clinical laboratory and conduct our tests, worldwide or in particular jurisdictions, which would adversely impact our diagnostic testing business, operating results, and financial condition. Our HCT / P products are subject to

extensive government regulation and our failure to comply with these requirements could cause our business to suffer. In the United States, we provide donor egg and sperm for fertility treatments, in addition to fertility cryopreservation services and newborn stem cell storage (cord blood and cord tissue). Donated reproductive tissues, including eggs and sperm, as well as cord blood and cord tissue, are regulated to by the FDA as ~~human cells, tissues and cellular or tissue- based products (HCT / Ps)~~. In the United States, we are marketing these HCT / Ps pursuant to Section 361 of the ~~Public Health Service Act (~~ PHSA ~~)~~ and 21 C. F. R. Part 1271 of FDA' s regulations. ~~The so- called~~ **Products subject to regulation as** " 361 HCT / Ps " are not currently **required** ~~subject to the FDA requirements~~ to obtain marketing authorizations, so long as they meet certain criteria set forth in FDA regulations. However, HCT / Ps regulated as 361 HCT / Ps are currently subject to requirements relating to registering facilities and listing products with the FDA, as well as stringent requirements relating to processing, storing, labeling and distributing HCT / Ps, including, screening and testing for tissue donor eligibility, providing required labeling information, record keeping and adverse event reporting. If we fail to comply with these requirements, we could be subject to FDA allegations of noncompliance or enforcement action, including, for example, warning letters, fines, injunctions, product recalls or seizures, and, in the most serious cases, criminal penalties. To be regulated as 361 HCT / Ps, these products must meet the FDA' s criteria to be considered " minimally manipulated " and intended for " homologous use, " among other requirements. HCT / Ps that do not meet the criteria to be considered 361 HCT / Ps are subject to the FDA' s regulatory requirements applicable to medical devices, biologics or drugs, including, importantly, the requirement for premarket review and approval or clearance prior to marketing. We believe our HCT / Ps are regulated solely under Section 361 of the PHSA, and therefore, we have not sought or obtained 510 (k) clearance, PMA approval, or licensure through a Biologics License Application (BLA) for such HCT / Ps. However, the FDA could disagree with our determination that these human tissue products are 361 HCT / Ps and could determine that these products are biologics requiring a BLA or medical devices requiring 510 (k) clearance or PMA approval, and could require that we cease marketing such products and / or recall them pending appropriate clearance, approval or licensure from the FDA, which would adversely affect our business. In addition, the FDA may in the future modify the scope of its enforcement discretion with respect to 361 HCT / Ps or change its position on which current or future products qualify as 361 HCT / Ps, or determine that some or all of our HCT / P products may not be lawfully marketed without a marketing authorization. Any regulatory changes could have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring pre- market clearance or approval and compliance with additional post- market regulatory requirements with respect to those products. Disruptions at the FDA and other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA, foreign agencies and notified bodies to review and clear, approve or certify new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s, foreign agencies' and notified bodies' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s, foreign agencies' and notified bodies' ability to perform routine functions. Average review times at the FDA, foreign agencies and notified bodies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, foreign agencies and notified bodies and other agencies may also slow the time necessary for new drugs and medical devices or modifications to cleared or approved drugs and medical devices to be reviewed, approved and / or certified by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. ~~Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of foreign and domestic manufacturing facilities. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA, other regulatory authorities, or notified bodies from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, other regulatory authorities or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.~~ In the EU, notified bodies must be officially designated to certify products and services in accordance with the EU MDR and EU IVDR. ~~Several~~ **Their designation process, which is significantly stricter under the new Regulations, has experienced considerable delays. Despite a recent increase in designations, the current number of** notified bodies ~~have been~~ designated under the ~~EU MDR but only a few~~ **new Regulations remains significantly lower than the number of** notified bodies ~~have been~~ designated under the **previous regimes** ~~EU IVDR so far~~. The ~~COVID- 19 pandemic has significantly slowed down their designation process and the~~ current designated notified bodies are **, therefore,** facing a **backlog** ~~large amount~~ of requests ~~with the new regulations~~ , **and** ~~as a consequence of which~~ review times ~~may~~ have lengthened. This situation may impact the ability of our notified body to timely review and process our regulatory submissions and perform its audits. Ethical, legal and social concerns related to the use of genetic information, sperm and egg selection services and stem cells could reduce demand for our service offerings. Genetic testing, sperm and egg selection services and the use of stem cells have raised ethical, legal and social issues regarding privacy and the appropriate uses of information related to these services. Government authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. They also could limit, regulate or prohibit (1) sperm and egg

selection services or (2) the use of stem cells. Ethical, legal or social concerns may lead patients to refuse to use, or physicians to be reluctant to order or recommend, genetic tests, sperm and egg selection services and stem cell storage services even if permissible. These and other ethical, legal and social concerns may limit market acceptance and adoption of our service offerings or reduce the potential markets for our service offerings, either of which could have an adverse effect on our business, financial condition and results of operations. The costs of complying with the requirements of federal, state and foreign laws pertaining to the privacy and security of personal information, including health related information and the potential liability associated with failure to do so could materially adversely affect our business. Numerous laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability and integrity of personally identifiable information (PII), including protected health information (PHI). We collect and process PII in multiple ways in our various business lines and are subject to risk associated with compliance with many of these laws and regulations. Some of our businesses expose us to increasingly stringent regulations for handling personal information (where, for example, we collect or process PII deemed to be sensitive by regulatory authorities, such as PHI). Under U. S. law, HIPAA establishes national privacy and security standards for protection of PHI by covered entities and the business associates with whom such entities contract for services. HIPAA requires both covered entities and business associates to develop and maintain policies and procedures for PHI that is used or disclosed, and to adopt administrative, physical and technical safeguards to protect PHI. Mandatory penalties for HIPAA violations can be significant. A single breach incident can result in violations of multiple standards. If a person knowingly or intentionally obtains or discloses PHI in violation of HIPAA requirements, criminal penalties may also be imposed. We maintain technical, organizational and contractual safeguards that we believe are reasonable and appropriate to protect the privacy and security of PHI and other personally identifiable information consistent with applicable laws and our contractual obligations; however, we may not be able to prevent incidences of inappropriate use or unauthorized access to PHI by our employees, contractors or external factors, despite the safeguards. Any such breaches of our systems or those of our vendors, customers or other third parties could result in exposure to liability under federal and state laws and / or under our contractual arrangements and could adversely impact our business. We are also subject to various other laws in the United States such as Section 5 (a) of the Federal Trade Commission Act, which requires 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 and the CCPA, which gives California residents certain rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. ~~Further, the California Privacy Rights Act, which went into effect on January 1, 2023, significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk processing, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement.~~ Similar laws have been ~~proposed or~~ enacted in other states and **proposed** at the federal level, and ~~when passed,~~ such laws may have potentially conflicting requirements that ~~would~~ make compliance challenging. We are also subject to laws and regulations in countries other than United States covering data privacy and the protection of health-related and other personal information. EU and EEA member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the GDPR imposes stringent operational requirements for processors and controllers of personal data in the context of an establishment in the EEA or the processing of personal data of individuals within the EEA and increases the scrutiny of transfer of personal data from the EEA. Following the UK' s withdrawal from the EEA and the EU, and the expiry of the transition period, companies will have to comply with the GDPR and the GDPR as incorporated into the UK national law (the UK GDPR). In addition, countries of the EEA may impose further obligations relating to the processing of genetic, biometric or health data, which could further add to our compliance costs and limit how we process this information. Some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the GDPR, and subject to additional compliance obligations and to local law derogations. We may be subject to diverging requirements under EU member state laws and UK law. We are also subject to China' s Personal Information Protection Law (PIPL), which imposes requirements regarding processing PII, data localization and cross- border transfers of PII, as well as a number of other laws in the Asia Pacific area ~~,~~**.** As these laws develop, we may need to make operational changes to adapt to these diverging rules, which could increase our costs and adversely affect our business. Compliance with U. S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Any failure or perceived failure by us to comply with privacy or security laws, policies, legal obligations or industry standards or any security incident that results in the unauthorized release or transfer of PII may result in governmental enforcement actions and investigations including by European Data Protection Supervisory Authorities, fines and penalties, litigation, orders to cease or change our data processing activities, enforcement notices, assessment notices for a compulsory audit and / or civil claims (including class actions), adverse publicity and reputational damage. Such failures could have a material adverse effect on our financial condition and operations. If the third parties we work with violate applicable laws, contractual obligations or suffer a security breach, such violations may also put us in breach of our obligations under privacy laws and regulations and could in turn have a material adverse effect on our business. When we acquire companies or business that engage **in** personal data processing, we may become subject to additional regulation or scrutiny, particularly if such activity is different in nature from what we have done in the past. For example, with the recent addition of cord blood and cord tissue storage (and other cryostorage) businesses, we interact directly with our

customers and collect and maintain personal information regarding our customers and donors. Acquisitions like this could subject us to additional regulatory and consumer liability risk and the cost of analyzing and integrating new privacy compliance programs. Changes in legislation and government regulation of the health care industry both in the United States and internationally, as well as third- party payors' efforts to control the costs of health care could materially adversely affect our business. The ACA made extensive changes to the delivery of health care in the United States. Among the provisions of the ACA, of greatest importance to the medical device industry and pharmaceutical industry are the following: • Establishment of the Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; • Payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models; • Establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and • An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23. 1 % and 13 % of the average manufacturer price for most branded and generic drugs, respectively. These measures could result in decreased net revenues or increased expenses from our fertility, office and surgical portfolios and decrease potential returns from our development efforts. Other legislative changes **which impact the medical device and pharmaceutical industry** have been proposed and adopted since the ACA was enacted ~~. The~~ **, including, the** Budget Control Act of 2011, **which,** among other things, included aggregate reductions to Medicare payments to providers **and** ~~. In addition,~~ the Medicare Access and CHIP Reauthorization Act of 2015, **which,** among other things, ~~repealed~~ **replaced and changed** the formula by which Medicare made annual payment adjustments to physicians and ~~replaced the former formula with fixed annual updates and a new system of incentive payments began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on March 11, 2021, President Biden signed~~ the American Rescue Plan Act of 2021 ~~into law~~, which ~~eliminates~~ **eliminated** the statutory Medicaid drug rebate cap ~~, currently set at 100 % of a drug' s average manufacturer price (AMP), beginning January 1, 2024. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated and the impact of the IRA on the pharmaceutical industry cannot yet be fully determined~~ . In foreign countries where we market our products, recent healthcare reform has taken place as well. For instance, in December 2021, the EU Regulation No 2021 / 2282 on Health Technology Assessment (HTA) amending Directive 2011 / 24 / EU was adopted. ~~While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once the regulation becomes applicable, it will have a phased implementation depending on the concerned products.~~ This ~~regulation~~ **Regulation** intends to boost cooperation among EU member states in assessing health technologies, including certain high- risk medical devices, and ~~providing~~ **provide** the basis for cooperation at the EU level for joint clinical assessments in these areas. **It** ~~The regulation~~ will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the ~~most~~ **highest** potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. We expect that additional state, federal and foreign health care reform measures will be adopted in the future, including those initiatives affecting coverage and reimbursement for our products, any of which could limit the amounts that federal state and foreign governments will pay for health care products and services, which could adversely affect the growth of the market for our products or demand for our products, or result in additional pricing pressures. Also, any adoption of health care reform proposals on a state- by- state basis could require us to develop state- specific marketing and sales approaches. We cannot predict the effect such reforms or the prospect of their enactment may have on our business. In addition, third- party payors, whether governmental or commercial, whether inside the United States or abroad, increasingly attempt to contain or reduce the costs of health care. These cost- control methods include prospective payment systems, capitated rates, group purchasing, redesign of benefits, requiring pre- authorizations or second opinions prior to certain medical procedures, encouragement of healthier lifestyles and exploration of more cost- effective methods of delivering health care. Although cost controls or other requirements imposed by third- party payors have not historically had a significant effect on contact lens prices or distribution practices, this could change in the future and could adversely affect our business. We may enroll as in- network providers and suppliers with certain payors. Although, becoming an in- network provider or enrolling as a supplier means that we have agreed with these payors to provide certain of our tests at negotiated rates, it does not obligate any physicians to order our tests or guarantee that we will receive reimbursement for our tests from these or any other payors at adequate levels. Thus, these payor relationships, or any similar relationships we may establish in the future, may not result in acceptable levels of reimbursement for our tests or meaningful increases in our physician customer base. We cannot predict whether, under what circumstances, or at what payment levels payors will cover and reimburse for our tests. If we fail to establish and maintain broad coverage and reimbursement for our tests, our ability to generate increased revenue and grow our test volume and customer base could be limited and our future prospects and our business could suffer. Laws pertaining to health care fraud and abuse could materially

adversely affect our business. We may be subject to various federal, state and foreign laws pertaining to health care fraud and abuse, including anti- kickback, physician self- referral false claims and physician payment transparency laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including our commercial laboratory operations and how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation; • the federal physician self- referral prohibitions, commonly known as the Stark Law, which generally prohibit entities from billing a patient or the Medicare or Medicaid programs for certain designated health services, including clinical laboratory services, when the physician ordering the service, or any member of such physician' s immediate family, has a financial interest, such as an ownership or investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition. These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral; • the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute or Stark Law constitutes a false or fraudulent claim for purposes of the civil False Claims Act; • the federal **Civil Monetary Penalties Law, which, among other things, authorizes the imposition of civil monetary penalties, assessments, and exclusion against an individual or entity based on a variety of prohibited conduct, including, but not limited to, offering remuneration to a federal healthcare program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive healthcare items or services from a particular provider; • the federal** Health Insurance Portability and Accountability Act of 1996, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments and other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners including physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers and self- pay patients; some state laws that require biotechnology companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug and device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws that require the registration of sales representatives. In addition, federal government price reporting laws, among other things, require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and / or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, including Medicare, Medicaid, Veterans Administration health programs and TRICARE. Similarly, if the physicians or other providers or entities with whom we do business are found to be non- compliant with applicable laws, they may be subject to sanctions, which could indirectly have a negative impact on our business, financial condition and results of operations. Because of the complex and far- reaching nature of these laws, we cannot be assured that we would not be required to alter one or more of our practices to be in compliance with these laws. Any violations of these laws or regulations could result in a material adverse effect on our business, financial condition and results of operations. In addition, changes in these laws, regulations, or administrative or judicial interpretations, may require us to further change our business practices or subject our existing business practices to legal challenges, which could have a material adverse effect on our business. Risks Relating to Interest and Foreign Exchange Rates, Debt and Equity Exchange rate fluctuations and foreign currency hedges could adversely affect our financial results. As a result of our international operations, currency exchange rate fluctuations may affect our results of operations and financial position. Our most significant currency exposures are the British pound, Euro and Japanese yen. We expect to generate an increasing portion of our revenue and incur a significant portion of our expenses in currencies other than U. S. dollars. To the extent we are unable to materially offset non- functional currency flows, exchange rate fluctuations could have a positive or negative impact

on our financial condition and results of operations. Because our consolidated financial results are reported in U. S. dollars, if we generate sales or earnings in other currencies, the translation of those results into U. S. dollars can result in a significant increase or decrease in the amount of those sales or earnings and can make it more difficult for our stockholders to understand the relative strengths or weaknesses of the underlying business on a period- over- period comparative basis. Although we may enter into foreign exchange agreements with financial institutions to reduce our net exposure to fluctuations in foreign currency values relative to our non- functional currency obligations or balances, they would not eliminate that risk entirely. We are vulnerable to interest rate risk with respect to our debt. We are subject to interest rate risk in connection with the issuance of variable and fixed- rate debt. In order to maintain a desired mix of fixed- rate and variable- rate debt, from time to time we may use interest rate swap agreements to fix a portion of our variable- rate debt as further described in Note 13. Financial Derivatives and Hedging of the Consolidated Financial Statements. We may not be successful in structuring such swap agreements to manage our risks effectively, which could adversely affect our business. ~~Effective February 1, 2023, the Company transitioned its credit agreements from the London Interbank Offered Rate (LIBOR) to the Secured Overnight Financing Rate (" SOFR"). The Company adopted this guidance prospectively on February 1, 2023, and it did not have a material impact on our business.~~ Our indebtedness could adversely affect our financial health and prevent us from fulfilling our debt obligations. We have now and expect to continue to have a significant amount of indebtedness. Our indebtedness could: • increase our vulnerability to general adverse economic and industry conditions; • require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures, acquisitions, research and development efforts and other general corporate purposes; • limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; • place us at a competitive disadvantage compared to our competitors that have less debt; • result in greater interest rate risk and volatility; • limit our ability to borrow additional funds; and • make it more difficult for us to satisfy our obligations with respect to our debt, including our obligation to repay our credit facilities under certain circumstances, or refinance our indebtedness on favorable terms or at all. Our credit facilities contain financial and other restrictive covenants that could limit our ability to engage in activities that may be in our long- term best interests. Our failure to comply with those covenants could result in an event of default which, if not cured or waived, could result in the acceleration of all of our debt, which could adversely affect our business. Volatility in the securities markets, interest rates, and other factors could substantially increase our defined benefit plan costs. We sponsor a defined benefit plan for certain employees in the United States. This defined benefit plan is funded with trust assets invested in a diversified portfolio of securities and other investments. Changes in interest rates, mortality rates, early retirement rates, investment returns, discount rates and the market value of plan assets can affect the funded status of our defined benefit plan and cause volatility in the net periodic benefit cost and future funding requirements of the plan. A significant increase in our obligations or future funding requirements could increase our cash requirements and adversely affect our business. Risks Relating to Taxes Changes in tax laws, examinations by tax authorities, and changes in our geographic composition of income could adversely affect our ~~business~~ **financial results** . **We** ~~Income taxes and other taxes~~ are ~~based on enacted~~ **subject to U. S. and foreign** tax laws **that may** ~~and the results of operations in each jurisdiction. Taxes could significantly increase due to changes~~ - **change** ~~in tax laws or changes in our interpretation of those laws~~ . ~~Changes in tax laws could result from a framework being developed~~ **The base erosion and profit shifting (BEPS) project undertaken** by the Organisation for Economic Co-operation and Development (OECD) ~~, a global policy forum, that, if implemented,~~ includes **Pillar Two,** a global minimum tax rate of 15 % **that may adversely affect our provision for** ~~. Taxes could also significantly increase due to changes in accounting guidance. Income~~ **income** taxes **. We are subject to the examination of our tax returns** and other **matters by** ~~taxes could significantly increase based on the resolution of~~ tax ~~authority~~ **authorities** ~~examinations~~ . Tax authorities could ~~challenge our interpretations of tax laws and estimates we use to calculate taxes. Tax authorities could also~~ challenge our positions related to transfer pricing and intercompany transactions, including the valuation of intangible assets. Tax examinations can result in costly litigation with significant interest and penalties and ultimate settlement can take several years. For example, we have engaged (and expect to continue to engage) with tax authorities over tax positions we have taken in connection with **our** acquisitions, and such examinations could cause us to incur significant expense (and adverse determinations by the tax authority could result in penalties) **which could have an adverse effect on our financial results** . Our effective tax rate could fluctuate based on the geographic composition of income, which could significantly change based on our business results and acquisitions. Our effective tax rate could also fluctuate based on changes in estimates, changes in excess tax benefits from share- based compensation, changes in non- deductible expenses, and the valuation of deferred tax assets and liabilities. These fluctuations could have an adverse effect on our ~~business~~ **financial results** .