Risk Factors Comparison 2025-01-31 to 2024-01-31 Form: 10-K

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

You should consider each of the following risk factors, which could materially affect our business, financial condition, or future results of operations. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, or future results of operations. In addition, the global economic environment **may** ~~and additional or unforeseen effects from COVID- 19~~ amplify many of these risks. RISKS RELATING TO OUR BUSINESS OUR MARKETS ARE HIGHLY COMPETITIVE, AND CUSTOMERS MAY CHOOSE TO PURCHASE OUR COMPETITORS' PRODUCTS OR SERVICES OR MAY NOT ACCEPT ROBOTIC- ASSISTED MEDICAL PROCEDURES, WHICH COULD RESULT IN REDUCED REVENUE AND LOSS OF MARKET SHARE. Robotic- assisted surgery with a da Vinci surgical system or robotic- assisted bronchoscopy with an Ion endoluminal system are technologies that compete with established and emerging treatment options in reconstructive medical procedures or disease management. These competitive treatment options include open surgery, conventional MIS, drug therapies, radiation treatment, and other emerging diagnostic and interventional surgical approaches. Some of these procedures are widely accepted in the medical community and, in many cases, have a long history of use. Technological advances could make such ~~treatments~~ **treatment options** more effective or less expensive than using our products, which could render our products obsolete or unmarketable. **Also,** ~~Studies~~ **studies** could be published that show that other treatment options are more beneficial and / or cost-effective than robotic- assisted medical procedures. **We cannot be certain that physicians, or their patients, will choose our products to replace or supplement established treatment options or that our products will continue to be competitive with current or future technologies.** For example, in 2023, certain drugs initially approved for use in diabetes patients gained market acceptance for use in weight loss **treatment** following FDA approvals for weight loss indications. The availability and effectiveness of weight loss drugs have ~~adversely impacted~~ **reduced the number of bariatric procedures performed, including those bariatric procedures performed using** our da Vinci surgical system **, as** ~~bariatric procedures by causing~~ some patients ~~to~~ reconsider the surgical **treatment** option. At this time, it is difficult to predict the long- term market impact of these drugs, including their long- term efficacy **as weight loss drugs** and potential drawbacks. ~~We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will continue to be competitive with current or future technologies.~~ Additionally, we **currently** face **,** or ~~expect to face~~ **anticipate facing,** competition from companies **with products used in open or MIS surgeries, including laparoscopy and alternative multi- port, single- port, or endoluminal systems. We also compete with companies providing other therapeutic approaches for addressing target clinical conditions, as well as companies developing diagnostic solutions** that ~~develop~~ **could serve as alternatives to current** or **planned Intuitive offerings. Companies that** have ~~developed wristed,~~ **introduced products in the field of** robotic- assisted ~~, or computer- assisted medical systems and products. Companies have introduced products in the field of robotic~~ medical procedures **,** or have made explicit statements about their efforts to enter the field **,** ~~including~~ **include** , but **are** not limited to, the following ~~companies~~ : ~~Asensus Surgical, Inc.;~~ Beijing Surgerii Robotics Company Limited; CMR Surgical Ltd.; **Distalmotion SA; Harbin Sizhe Rui Intelligent Medical Equipment Co., Ltd.;** Johnson & Johnson **; Karl Storz SE & Co. KG** ; Medicaroid Corporation; Medtronic plc; meerecompany Inc.; Noah Medical; Shandong Weigao Group Medical Polymer Company Ltd.; Shanghai Microport Medbot (Group) Co., Ltd.; ~~and~~ Shenzhen Edge Medical Co., Ltd **.; and SS Innovations International, Inc** . Other companies with substantial experience in industrial robotics could potentially expand into the field of medical robotics and become competitors. **Additionally, we expect increasing competition within China for robotic-assisted surgical systems. We may not be able to maintain or improve our competitive position against current or potential competitors, especially those with greater resources.** Our revenues may be reduced due to pricing pressure ~~or eliminated~~ if our competitors develop and market products that are more effective or less expensive than our products. If we are unable to compete successfully, our revenues will suffer, which could have a material adverse effect on our business, financial condition, or result of operations ~~. We may not be able to maintain or improve our competitive position against current or potential competitors, especially those with greater resources~~ . In addition, third- party service providers that service da Vinci surgical system and Ion endoluminal system operators may emerge and compete with us on price or offerings. To date, substantially all of our customers have sourced services on their systems from us through service contract commitments or time and materials contracts. Furthermore, there are third- party service providers offering consulting services targeted at analyzing the cost- effectiveness of hospitals' robotic- assisted medical programs, including procedures performed, placement of systems, and consumption of instruments and accessories. We currently provide similar services and analysis to our customers, but it is difficult to assess the impact that this may have on our business. If we are unable to compete successfully with any third- party service providers, our revenues may suffer ~~. MACROECONOMIC CONDITIONS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS~~ , FINANCIAL CONDITION, OR RESULTS OF OPERATIONS..... may be adversely impacted, all of which could have a material adverse effect on our business, financial condition, or ~~results~~ **result** of operations . Additionally, with economic uncertainty,..... could result in deferred or canceled procedures . WE ARE SUBJECT TO A VARIETY OF RISKS DUE TO OUR OPERATIONS OUTSIDE OF THE U. S. We manufacture, perform research and development activities, and distribute our products in OUS markets. Revenue from OUS markets accounted for approximately **33 %,** 34 ~~%, 33~~ %, and 33 % of our revenue for the years ended December 31, **2024,** 2023, **and** 2022 ~~, and 2021~~ , respectively. Our OUS operations are, and will continue to be, subject to a number of risks including: • the failure to obtain or maintain the same degree of protection against infringement of our intellectual property rights due to differing intellectual property protection

laws in OUS countries from those in the U. S.; • multiple OUS regulatory requirements that are subject to change and that could impact our ability to manufacture and sell our products; • changes in tariffs, trade barriers, and regulatory requirements **, such as the enactment of tariffs on goods imported into the U. S. including, but not limited to, the proposed tariff on goods imported from Mexico where we manufacture a significant majority of our instruments and accessories that we sell** ; • protectionist laws, policies, and business practices **and nationalistic campaigns** that favor local competitors or lead ~~to~~ non- U. S. customers **to** ~~favoring~~ --- **favor** domestic technology solutions **over imports** , which could slow our growth **, increase our costs, or make our products less competitive** in OUS markets; • local or national regulations that make it difficult or impractical to market or use our products; • U. S. relations with the governments of the other countries in which we operate; • the inability or regulatory limitations on our ability to move goods across borders; • the risks associated with foreign currency exchange rate fluctuations; • the difficulty in establishing, staffing, and managing OUS operations, including differing labor relations; • the expense of establishing facilities and operations in new foreign markets; • the building and maintenance of an organization capable of supporting geographically dispersed operations, including appropriate business procedures and controls; • **compliance with** anti- corruption laws, such as the U. S. Foreign Corrupt Practices Act (" FCPA "), **UK Bribery Act of 2010 (" UK Bribery Act "),** and other local laws prohibiting corrupt payments to government officials; • **adherence to** antitrust and anti- competition laws; • economic weakness, including inflation, or political instability in particular foreign economies and markets, including exposure to a higher degree of financial risk if we extend credit to customers in these economies; and • business interruptions due to natural disasters, outbreak of disease, climate change, and other events beyond our control. **We** ~~For example, in Israel, we have certain research and development operations primarily related to digital products. Depending on the length and extent of the conflict between Israel and Hamas, there may be adverse impacts to certain research and development timelines. Also, we~~ have increased, and will continue to increase, our operations in China. There is inherent risk, based on the complex relationships between China and the U. S., that political, diplomatic, military, or other events could result in business disruptions, including increased regulatory enforcement against companies, tariffs, trade embargoes, or export restrictions. Tariffs increase the cost of our products and the components and raw materials that go into making them. These increased costs adversely impact the gross margin that we earn on our products. Tariffs can also make our products more expensive for customers, which could make our products less competitive and reduce consumer demand. Countries may also adopt other measures, such as controls on imports or exports of goods, technology, or data, which could adversely impact our operations and supply chain and limit our ability to offer our products and services as designed. These measures can require us to take various actions, including changing suppliers and restructuring business relationships. Changing our operations in accordance with new or changed trade restrictions can be expensive, time- consuming, disruptive to our operations and distracting to management. Such restrictions can be announced with little or no advance notice, and we may not be able to effectively mitigate all adverse impacts from such measures. Political uncertainty surrounding trade and other international disputes could also have a negative effect on consumer confidence and spending. **Additionally, our joint venture works with and relies on a number of dealers, distributors, and other third parties to commercialize and deliver our products.** Any of these events could reduce customer demand, increase the cost of our products and services, or otherwise have a materially adverse impact on our customers' and suppliers' businesses or results of operations. For example, in 2020, the U. S. government amended the Entity List rules to expand the requirement to obtain a license prior to the export of certain technologies. In addition, in 2020, a new U. S. regulation seeks to prohibit the U. S. government from contracting with companies who use the products or services of certain Chinese companies. ~~We believe that~~ **Based on our current understanding of** these regulations **, they** do not materially adversely impact our business at this time ~~but~~ **. However, we** cannot predict the impact that additional regulatory changes may have on our business in the future. These actions or similar actions may result in policies and regulations in response that could adversely affect our business operations in China or may otherwise limit our ability to offer our products and services in China and other parts of the world. ~~Additionally~~ **In China, we have seen increasing competition in the robotic- assisted surgical system industry from domestic companies as well as a broader central government focus on systematic governance. For example** , in July 2023, the Chinese government launched a ~~one- year anti- corruption~~ campaign targeting the healthcare sector. **This campaign has resulted in heightened scrutiny by medical institutions with respect to initiating tenders, with some tenders being canceled or delayed without a timeline.** The ~~efforts~~ **extent and impact** of this campaign **on our business remains uncertain. In 2024,** ~~largely aim to curb kickbacks and corruption among individuals who have exploited their~~ -- **the effects** ~~positions within medical institutions. As a result~~ of this ~~anti- corruption~~ campaign, **combined** ~~the medical institutions have heightened their scrutiny~~ with ~~respect to initiating tenders. Therefore, some tenders were cancelled or delayed without an updated timeline. In~~ the **competitive dynamics in China** ~~third and fourth quarters of 2023~~ , ~~the effect of this anti- corruption campaign~~ contributed to fewer systems being placed in China **than we anticipated** . Currently, the extent **and** ~~of the~~ impact of this ~~anti- corruption~~ campaign **and the competitive dynamics in China** on our business remains uncertain. **In Israel, we have certain research and development operations primarily related to digital products. Depending on the length and extent of conflicts in the Middle East, including Israel and Iran, there may be adverse impacts to certain research and development timelines. In the UK,** ~~Following~~ **following** a national referendum and enactment of legislation by the government ~~of the UK~~ , the UK formally withdrew from the EU and ratified a trade and cooperation agreement governing its relationship with the EU. The EU – UK Trade and Cooperation Agreement (the " TCA ") was applied provisionally as of January 1, 2021, and entered into force on May 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation will not be implemented in the UK, and previous legislation that sought to mirror the EU Medical Devices Regulation in the UK law has been revoked. The regulatory regime for medical devices in Great Britain continues to be based on the requirements derived from previous EU legislation, and the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation going forward. On ~~June 26~~ **January 9** , ~~2022~~ **2024** , the MHRA published **a roadmap setting out** its **plans and timelines towards** ~~response to a 10- week consultation on~~ the ~~future~~ **reform of**

the ~~regulation~~ **regulatory** ~~of~~ **framework for** medical devices in the UK. Regulations implementing **core elements of** the new **framework are intended** ~~regime were originally scheduled~~ to **be** ~~come into force~~ in **place by** ~~July 2023 but the MHRA has confirmed that it is aiming for the core aspects of the new regime to apply from July~~ 2025. **Pending such reform of** ~~Devices which have valid CE certification issued by EU notified bodies under~~ the **UK regulatory framework, the** ~~EU Medical Devices Regulation or Medical Devices Directive are subject to transitional arrangements. The~~ Government has confirmed that general medical devices compliant with the EU Medical Devices Directive 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. Medical devices, including custom- made devices, compliant with the EU Medical Devices Regulation can be placed on the Great Britain market up until June 30, 2030 ~~. Following these transitional periods, it is expected that all medical devices will require a UK Conformity Assessment mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the regulations coming into force. However, from July 2025, products that do not have existing and valid CE certification under the EU Medical Devices Directive or EU Medical Devices Regulation and are therefore not subject to the transitional arrangements will be required to carry the UKCA mark if they are to be sold into the market in Great Britain. UKCA marking will not be recognized in the EU~~ . The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in Great Britain (England, Scotland and Wales) and continue to be based on EU law. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization- related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the " rules of origin " criteria will need to be reviewed. Depending on which countries products will ultimately be sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in Great Britain. These developments, or the perception that any related developments could occur, have had and may continue to have a material adverse effect on global economic conditions and financial markets, and our business would likely be impacted and the demand for our products could be depressed. **The** ~~In addition, the~~ U. S. federal government has made changes to the U. S. trade policy, including entering into a successor to the North American Free Trade Agreement (" NAFTA "), known as the United States- Mexico- Canada Agreement (" USMCA "), effective as of July 1, 2020. In addition, the U. S. federal government has implemented ~~, or is considering the imposition of,~~ tariffs on certain foreign goods **and may implement additional tariffs on foreign goods. For example, on January 20, 2025, the U. S. presidential administration re- confirmed its intention to impose a 25 % tariff on imports from Mexico and Canada into the United States as early as February 1, 2025. As we currently manufacture a significant majority of our instruments and accessories in Mexicali, Mexico, a 25 % tariff on all imports from Mexico would increase the costs of our products manufactured in Mexico and adversely impact our gross profit** . Such tariffs and, if enacted, any further legislation or actions taken by the U. S. federal government that restrict trade, such as additional tariffs, trade barriers, and other protectionist or retaliatory measures taken by governments in Europe, Asia, and other countries, could adversely impact our ability to sell products and services in our OUS markets. Tariffs could increase the cost of our products and the components and raw materials that go into making them. These increased costs could adversely impact the gross margin that we earn on our products, which could make our products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit our ability to offer our products and services. ~~Furthermore~~ **The ultimate impact of any tariffs will depend on various factors** , ~~in~~ **including if any tariffs are ultimately implemented, the timing of implementation, and the amount, scope, and nature of the tariffs. In** certain markets, our OUS sales are denominated in U. S. dollars. As a result, an increase in the value of the U. S. dollar relative to foreign currencies could make our products less competitive and / or less affordable in those OUS markets. If we are unable to meet and manage these risks **noted above** , our OUS operations may not be successful, which would limit the growth of our business and could have a material adverse effect on our business, financial condition, or result of operations. WE ARE SUBJECT TO LITIGATION, INVESTIGATIONS, AND OTHER LEGAL PROCEEDINGS RELATING TO OUR PRODUCTS, CUSTOMERS, COMPETITORS, AND GOVERNMENT REGULATORS THAT COULD MATERIALLY ADVERSELY AFFECT OUR FINANCIAL CONDITION, DIVERT MANAGEMENT' S ATTENTION, AND HARM OUR BUSINESS. We are, and may become, subject to various legal proceedings and claims that arise in or outside the ordinary course of business. Certain current lawsuits and pending proceedings to which we are party, including purported class actions, product liability litigation, and patent litigation, are described in Note 8 to the Consolidated Financial Statements included in Part II, Item 8. In particular, our business exposes us to significant risks of patent claims, product liability claims, and competition claims (including antitrust claims), many of which are common in the medical device industry. For example, product liability claims have been brought against us by, or on behalf of, individuals alleging that they have sustained personal injuries and / or death as a result of purported product defects, the alleged failure to warn, and / or the alleged inadequate training by us of physicians regarding the use of the da Vinci surgical ~~system~~ **systems** . The individuals who have brought the product liability claims seek recovery for their alleged personal injuries and, in many cases, punitive damages. ~~Current product~~ **Product** liability claims have resulted in negative publicity regarding our Company, and **ongoing or future** ~~these and any other~~ product liability or negligence claims or product recalls **could** also ~~could~~ harm our reputation. Refer to our risk factor titled " Negative publicity, whether accurate or inaccurate, concerning our products or our company could reduce market acceptance of our products and could result in decreased product demand and reduced revenues " for additional risks related to the potential effects of negative publicity on our business. Also, antitrust claims have been brought against us by third parties looking to compete in the instruments or servicing space and by certain customers. The outcome of these product liability claims and other legal proceedings cannot be predicted with certainty. We purchase and maintain business insurance for certain liabilities and self- insure our product liability claims through a fronting policy. We cannot determine whether our existing business insurance program would be sufficient to cover the costs or potential losses

related to ~~these~~ **our** lawsuits and **legal** proceedings or otherwise be excluded under the terms of any insurance policy. **Additionally,** ~~Regardless~~ **regardless** of merit, litigation may be time- consuming and disruptive to our operations and cause significant legal costs (including settlements, judgments, legal fees, and other related defense costs) and diversion of management attention **. We could also be subject to governmental investigations in connection with some of these claims** . If we do not prevail in these legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that could have a material adverse effect on our business, financial condition, or results of operations. **WE OFFER USAGE-BASED ARRANGEMENTS, INCLUDING ALTERNATIVE CAPITAL ACQUISITION APPROACHES; AS A RESULT, WE ARE EXPOSED TO AN INCREASED RISK OF LOSSES OF REVENUE AND INCREASED CREDIT RISK, WHICH COULD ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS.** We **WE OFFER ALTERNATIVE CAPITAL ACQUISITION APPROACHES AND** ~~exposed to an increased risk of losses of revenue in any period where the usage decreases.Moreover~~ , **AS A RESULT** ~~our pricing is generally set based on the expected usage of the technology.Therefore~~ , ~~if utilization of our technology falls short of the anticipated levels~~ **WE ARE EXPOSED TO THE CREDIT RISK OF SOME OF OUR CUSTOMERS AND THE RISK OF LOSSES OF REVENUE** , **WHICH COULD RESULT IN MATERIAL LOSSES** ~~we may not be able to recover the costs associated with the technology,which could adversely affect our business,financial condition,or results of operations~~ .We believe customer financing through leasing is an important consideration for some of our customers and have experienced an increase in demand for customer financing.Lease financing arrangements have the effect of reducing cash flows at lease commencement and,instead,spread them over the life of the lease term,which increases the time taken to recover our product costs and can impact our liquidity.We may experience losses from a customer' s failure to make payments according to the contractual lease terms.Our exposure to the credit risks relating to our lease financing arrangements may increase if our customers are adversely affected by changes in healthcare laws,coverage,and reimbursement,economic pressures or uncertainty,or other customer-specific factors.Although we have programs in place that are designed to monitor and mitigate the associated risks,there can be no assurance that such programs will be effective in reducing credit risks relating to these lease financing arrangements.If the level of credit losses we experience in the future exceeds our expectations,such losses could have a material adverse effect on our financial condition or results of operations. **Certain of our leasing arrangements allow customers to cancel,return,or upgrade the systems leased prior to the end of the lease term without incurring a financial penalty.** We also lease our systems to certain qualified customers where the lease payments are based on their usage of the systems. ~~If~~ **While leases,including usage- based arrangements,enable our customers to upgrade and get access to new technologies faster,it may also enable competitors to more easily induce customers to switch to a competitor' s system.Furthermore,depending on the timing and terms of the upgrade transaction,the amount of revenue generated on the initial and upgraded lease arrangements may not,in the aggregate,generate the same amount of revenue that a traditional sale and trade- in transaction would.Also,if** customers do not perform a sufficient number of procedures on our systems leased under usage-based arrangements,it could impact our profitability on those **transactions** ~~arrangements and our overall results of operations~~ .Moreover,the usage of those systems ~~and related billings~~ could vary from quarter to quarter,which could result in higher variability in our revenue under those arrangements,including a significant reduction in revenue if the usage ends **.Additionally** , ~~fluctuations in our gross profit margins~~ if ~~utilization is different than our expectations,and unpredictable cash flows.Moreover,there is risk in forecasting future utilization of a system and,therefore,we may not set our usage- based rates high enough to maintain our gross profit margins.Additionally,certain of our leasing arrangements allow~~ customers ~~to cancel,~~ return ~~,~~ or ~~upgrade~~ **terminate** ~~the~~ **these arrangements prematurely** ~~systems leased prior to the end of the lease term without incurring a financial penalty~~ , ~~which~~ **it** could have a material adverse effect on our business,financial condition,or ~~results~~ **result** of operations. ~~If systems~~ could also **incur additional losses, as we may not** be ~~subject~~ **able** to ~~governmental investigations in connection with~~ **recover the remaining value of those returned assets, thereby negatively impacting our financial results. While leases, including usage- based arrangements, enable our customers to upgrade and get access to new technologies faster, it** ~~many~~ **may** ~~of~~ **also enable competitors to more easily induce customers to switch to such competitors' systems. Furthermore, depending on** ~~these~~ **the** ~~claims~~ **timing and terms of the upgrade transaction, the amount of revenue generated on the initial and upgraded lease arrangements may not, in the aggregate, generate the same amount of revenue that a traditional sale and trade- in transaction would** . OUR RELIANCE ON SOLE- AND SINGLE- SOURCED SUPPLIERS AND ABILITY TO PURCHASE AT ACCEPTABLE PRICES A SUFFICIENT SUPPLY OF MATERIALS COULD HARM OUR ABILITY TO MEET PRODUCT DEMAND IN A TIMELY MANNER OR WITHIN BUDGET. Some of the components necessary for the assembly of our products are currently provided to us by sole- sourced suppliers or single-sourced suppliers. We generally purchase components through purchase orders rather than long- term supply agreements and generally do not maintain large volumes of **components within our** inventory. While alternative suppliers exist and could be identified for single- sourced components, the disruption or termination of the supply of components, or inflationary pressure in our supply chain, could cause a significant increase in the costs of these components, which could affect our operating results. Certain of our sole- sourced suppliers or single- sourced suppliers could be adversely affected by the macroeconomic conditions, such as liquidity concerns in the broader financial services industry, that could result in delayed access or loss of access to their uninsured deposits or loss of their ability to draw on existing credit facilities involving a troubled or failed financial institution. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction, and damage our reputation and our brand. Furthermore, if we are required to change the manufacturer of a key component of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The time and processes associated with the verification of a new manufacturer could delay our ability to manufacture our products on schedule or within budget, which may have a material adverse impact on our

business, financial condition, or results of operations. In addition, our ability to meet customers' demands depends, in part, on our ability to timely obtain an adequate delivery of quality materials, parts, and components from our suppliers. An information technology systems interruption, including cyberattacks, could adversely affect the ordering, distribution, and manufacturing processes of our suppliers. **Current supply chain constraints include** ~~Difficulties~~ **difficulties** ~~remain~~ in obtaining a sufficient supply of **engineered raw** ~~semiconductor and other component~~ materials ~~,~~ and ~~we expect such difficulties~~ **certain subcontract suppliers being operationally challenged** to **meet our production requirements** ~~persist in the foreseeable future~~. **Additionally,** ~~Prices~~ **prices** of ~~such~~ materials ~~have also increased, and global~~ **for some components remain elevated from historical levels due to strong market demand or** supply **chain cost inflation** ~~has become constrained due to the increased demand for materials, including semiconductors, to support expansion of server and cloud networks as a greater proportion of the global population worked remotely, the introduction of 5G, and the continued electrification of vehicles~~. **If** ~~We engage in activities to seek to mitigate~~ such supply ~~disruptions by, for example, increasing our communications with our suppliers and modifying our purchase order coverage and inventory levels. Such global shortages in important components have resulted in, and will continue to cause, inflationary pressure in our supply~~ chain **constraints** ~~, which would impact our profits and profit margin. If shortages~~ and price increases in important supply- chain materials ~~in the semiconductor or other markets~~ continue, we could also fail to meet product demand, which would adversely impact our business, financial condition, or results of operations. NEW PRODUCT DEVELOPMENTS AND INTRODUCTIONS MAY ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. We develop and introduce new products with enhanced features and extended capabilities from time to time. We may introduce new products that target different markets than what our existing products target. The success of new product introductions depends on a number of factors including, but not limited to, timely and successful research and development, regulatory clearances, approvals, or certifications, establishment or maintenance of intellectual property rights, pricing, competition, market and consumer acceptance, ~~the~~ effective forecasting and management of product demand, inventory levels, ~~the~~ management of manufacturing costs and capacity, ~~the~~ management of supply costs, including mitigation of unforeseen supply chain disruptions for materials and components, and the risk that new products may have quality or other defects in the early stages of introduction. We invest substantially in various research and development projects to expand our product offerings. Our research and development efforts are critical to our **future** success, and ~~our~~ **such** research and development projects may not be successful. We may be unable to **successfully** develop and market new products ~~successfully~~, and the products we invest in and develop may not be well- received by customers or meet our expectations. Our research and development investments may not ~~generate significant operating income or~~ contribute to our future operating results for several years **or ultimately generate significant operating income**, and such **future** contributions may not meet our expectations or even cover the costs of such investments. In addition, the introduction or announcement of new products or product enhancements may shorten the life cycle of our existing products or reduce **the** demand for our current products, thereby offsetting any benefits of successful product introductions and potentially leading to challenges in managing **our** inventory of existing products. Our products are subject to various regulatory processes, and we must obtain and maintain regulatory approvals and certifications in order to sell our new products. If a potential purchaser believes that we plan to introduce a new product in the near future or is located in a country where a new product that we have introduced has not yet received regulatory clearance or certification, planned purchases may be deferred or delayed. In the past, we have experienced a slowdown in **the** demand for existing products in advance of new product introductions, and we may experience a slowdown in **such** demand in the future as well. It is also possible that a new product introduction could cause downward pressure on the prices of our existing products or require us to change how we sell our products, either of which could have material adverse effects on our revenues. If we fail to effectively develop new products and manage new product introductions in the future, our business, financial condition, or results of operations could be adversely impacted. WE MAY ENCOUNTER MANUFACTURING PROBLEMS OR DELAYS THAT COULD RESULT IN LOST REVENUE. Manufacturing our products is a complex process. We (or our critical suppliers) may encounter difficulties in scaling up or maintaining production of our products, including: • problems involving production yields; • quality control and assurance; • component supply shortages; • import or export restrictions on components, materials, or technology; • shortages of qualified personnel; and • compliance with state, federal, and foreign regulations. If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to develop or maintain larger- scale manufacturing capabilities or build new manufacturing capabilities or facilities on schedule or within budget, our ability to generate revenue and maintain **gross** profit margins as expected will be limited and our reputation in the marketplace could be damaged, all of which may have a material adverse impact on our business, financial condition, or results of operations. In addition, as we build new facilities for manufacturing capacity, the development of these facilities is subject to risks relating to our ability to complete our projects on schedule or within budget. Refer to our risk factor titled " We are subject to risks associated with real estate construction and development " for additional risks related to building our new manufacturing facilities. Also, after new manufacturing facilities are completed, we may encounter difficulties transferring our production lines from our existing facilities to the new facilities, which require qualification, validation, and regulatory approval and is subject to all of the risks highlighted above. Moreover, certain new manufacturing facilities are in foreign countries and in locations where we have not previously had manufacturing sites, both of which could increase the risks related to transferring our production lines. The facility transfers may require an increase in safety stock inventory to support the production line transfers, create a substantial backlog of customer orders, or increase costs while the production lines mature, all of which may have a material adverse impact on our business, financial condition, or results of operations. WE EXPECT GROSS PROFIT MARGINS TO VARY OVER TIME, AND CHANGES IN OUR GROSS PROFIT MARGINS COULD ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. Our gross profit margins have fluctuated from period to period, and we expect that they will continue to fluctuate in the future. Our gross profit margins may be adversely affected by numerous factors, including: •

changes in customer, geographic, or product mix, including the mix of ~~system~~ **systems** ~~models~~ sold or leased **; • changes in the mix of fixed payment or usage- based operating lease arrangements** ; • changes in the portion of sales involving a trade- in of another system and the amount of trade- in credits given; • our introduction of new products, which may have lower margins than our existing products; • our inability to maintain or reduce production costs; • changes in our pricing strategy **; • fluctuations in foreign currency exchange rates** ; • competition; • changes in production volume driven by demand for our products; • changes in material, labor, or other manufacturing- related costs, including the impact of foreign exchange rate fluctuations for foreign currency- denominated costs; • changes to U. S. and foreign trade policies, such as the enactment of tariffs on goods imported into the U. S. including, but not limited to, **the proposed tariff on** goods imported from Mexico where we manufacture a **significant** majority of our instruments **and accessories** that we sell; • inventory obsolescence, which may result from maintaining significant inventories of raw materials, components, and finished goods; • product recall charges; and • market conditions. If we are unable to offset the unfavorable impact of the factors noted above by increasing the volume of products shipped, reducing product manufacturing costs, or otherwise, our business, financial condition, or results of operations may be adversely affected ~~contagious diseases~~ **.MACROECONOMIC CONDITIONS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS,FINANCIAL CONDITION,OR RESULTS OF OPERATIONS.Macroeconomic conditions** ,such as ~~the~~ **inflationary pressure,changes to monetary policy,elevated interest rates,volatile** ~~current~~ **currency** ~~outbreak~~ **exchange rates,credit and sovereign debt concerns,concerns about slowed growth in China and other OUS markets,decreasing consumer confidence and spending,including capital spending,the introduction** of ~~a novel strain~~ **or changes in tariffs or trade barriers,and global or local recessions can adversely impact demand for our products,which could negatively impact our business,financial condition,or results** of ~~coronavirus~~ **operations.Recent macroeconomic conditions have been adversely impacted by geopolitical instability and military hostilities in multiple geographies** (**including the conflict between Russia and Ukraine and conflicts in the Middle East,including Israel and Iran),monetary and financial uncertainties,and the** COVID- 19 **pandemic.The results of these macroeconomic conditions,and the actions taken by governments,central banks,companies,and consumers in response,have previously resulted in,and may again in the future result in,higher inflation in the U.S.and globally,which could,in turn,lead to an increase in costs and may cause changes in fiscal and monetary policy,including additional increases in interest rates.Other adverse impacts of recent macroeconomic conditions have been,and may continue to be,supply chain constraints,logistics challenges,liquidity concerns in the broader financial services industry,and fluctuations in labor availability.We have experienced,and may continue to experience,supply chain constraints due to the current supply chain environment,including difficulties obtaining a sufficient supply of component materials used in our products.If interest rates remain elevated,access to credit may become more difficult,which may result in the insolvency of key suppliers,including single- source suppliers,which would exacerbate supply chain challenges.Cybersecurity breaches also remain a threat to our sustained supply continuity.Such supply chain constraints could cause us to fail to meet product demand,which could result in deferred or canceled procedures.Adverse developments that affect financial institutions,transactional counterparties,or other third parties,or concerns or rumors about these events,have in the past led to,and may in the future lead to,market- wide liquidity problems.For example,in 2023,Silicon Valley Bank (" SVB ")** ~~.To date~~ **was closed by the California Department of Financial Protection and Innovation** , ~~COVID- 19~~ **which appointed the U.S.Federal Deposit Insurance Corporation (" FDIC ")** ~~has~~ **as** ~~had~~ **receiver.Similarly,other institutions have been** ,and may continue to ~~have~~ **be** , **swept into receivership.Uncertainty may remain over liquidity concerns in the broader financial services industry,** ~~an~~ **and there may be unpredictable impacts to our business and our industry.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.Impacts from inflationary pressures could be more pronounced and materially** ~~adverse~~ **adversely** impact **aspects of our business where revenue streams and cost commitments are linked to contractual agreements that extend further into the future,as we may not be able to quickly or easily adjust pricing,reduce costs,or implement countermeasures.A higher inflationary environment can also negatively impact raw material,component,and logistics costs that,in turn,may increase the costs of producing and distributing our products.Furthermore,hospitals and distributors may choose to postpone or reduce spending due to financial difficulties or difficulties in obtaining credit to finance purchases of our products due to elevated interest rates and restraints** on **credit.Hospitals and distributors may also be adversely affected by liquidity concerns in the broader financial services industry,as described above,that could result in delayed access** ~~our~~ **or loss of access to uninsured deposits or loss of their ability to draw on existing credit facilities involving a troubled or failed financial institution.Certain hospitals are experiencing,and may continue to experience,financial and** ~~operations~~ **operational pressures** ~~,our supply chains and distribution systems,and our expenses,including~~ as a result of ~~preventive and precautionary measures that we,other businesses,and governments have taken and may continue to take.In addition,hospitals are experiencing~~ staffing shortages ~~and~~ **,the** supply chain ~~issues that~~ **environment,a decrease in government funding in healthcare,and elevated inflation,which** could impact their ability to **access capital markets and other funding sources,increase the cost of funding,or impede their ability to comply with debt covenants,all of which could impede their ability to** provide patient care ~~.Due to these impacts and measures~~ , **defer** ~~we have experienced,and may continue to experience,significant and unpredictable reductions in the demand for our products as healthcare customers divert medical resources and priorities towards the treatment of that disease.Also,our customers have delayed,cancelled,or redirected and,in the future,may delay,cancel,or redirect,planned capital expenditures in order to focus resources on COVID- 19 or in response to economic disruption related to COVID- 19.For example,as a result of the global COVID- 19 pandemic,in the first half of 2020,we experienced a significant decline in procedure volume in the U.S.and Western Europe,as healthcare systems diverted resources to meet the increasing demands of managing COVID- 19.In addition,U.S.and global public health bodies have,at times,recommended delaying~~ elective

surgeries ~~during~~ **,and impact** ~~the~~ **their** ~~COVID- 19 pandemic~~ **profitability.To the extent that hospitals face financial pressures** , **delayed access or loss of access to uninsured deposits,delayed access or loss of ability to draw on existing credit facilities,reductions in government spending,or higher interest rates,hospitals' ability or willingness to spend on capital equipment may be adversely impacted,all of** which ~~may continue to negatively impact the usage of our products and the number of da Vinci procedures performed.These delays in elective surgeries may create a patient backlog.The patients in this backlog may or may not use our products when their surgeries are ultimately performed.Also,as we are conducting IDE studies to support 510 (k) submission for da Vinci platforms and for seeking new indications,we may experience delays in obtaining new product approvals,clearances from the FDA,or approvals or certifications from foreign authorities or notified bodies,or we may experience delays in recruiting patients in our ongoing and planned clinical studies.As a result of the COVID- 19 outbreak,we experienced significant business disruptions,including restrictions on our ability to travel as well as distribute and service our products,temporary closures of our facilities and the facilities of our suppliers and their contract manufacturers,and a reduction in access to our customers due to diverted resources and priorities and the business hours of hospitals,as governments institute prolonged shelter- in- place and / or self- quarantine mandates.For example,our corporate headquarters and many of our operations,including certain of our manufacturing facilities,are located in California,which previously instituted risk reduction orders applicable to our employees in that region,significantly impacting the ability of our employees to get to their places of work to produce products and hampering our products from moving through the supply chain.These unprecedented measures to slow the spread of the virus taken by local governments and healthcare authorities globally,including the deferral of elective medical procedures and social distancing measures,had,and may continue to have,a negative impact on our operations and financial results.Furthermore,our future ways of working changes,including working from home,fully on- site,or in a hybrid fashion,may present additional risks,uncertainties,and costs that** could ~~affect our performance,including increased operational risk,uncertainty regarding office space needs,heightened vulnerability to cyberattacks due to remote work,potential reduced productivity,changes to our company culture,and increased costs to ensure our offices are safe and functional as hybrid offices that enable effective collaboration of both remote and in- person colleagues.In addition,the COVID- 19 pandemic adversely affected and may continue to adversely affect the economies and financial markets of many countries,which may result in a period of regional,national,and global economic slowdown or regional,national,or global recessions that could curtail or delay spending by hospitals and affect demand for our products as well as increased risk of customer defaults or delays in payments.Our customers may terminate or amend their agreements for the purchase,lease,or service of our products due to bankruptcy,lack of liquidity,lack of funding,operational failures,or other reasons.COVID- 19 and the current financial,economic,and capital markets environment,and future developments in these and other areas,present material uncertainty and risk with respect to our performance,financial condition,volume of business,or results of operations.Outbreaks of other epidemic,pandemic,or contagious diseases,such as,historically,the Ebola virus,Middle East Respiratory Syndrome,Severe Acute Respiratory Syndrome,or the H1N1 virus,could also divert medical resources and priorities towards the treatment of that disease.An outbreak of other contagious diseases could negatively affect hospital admission rates or disrupt our business similar to the impact of the COVID- 19 pandemic highlighted above.Any of these outbreaks could negatively impact the number of procedures performed and** have a material adverse effect on our business,financial condition,or results of operations. **Additionally** ~~WE COULD BE SUBJECT TO SIGNIFICANT UNINSURED LOSSES~~ **with economic uncertainty** , **an increase in unemployment rates** ~~WHICH MAY HAVE A MATERIAL ADVERSE IMPACT ON OUR BUSINESS~~ , ~~FINANCIAL CONDITION~~ **and increasing health insurance premiums** , ~~OR RESULTS OF OPERATIONS~~ **co- payments and deductibles may result in cost- conscious consumers pursuing fewer elective surgical procedures,which,in turn,could adversely affect procedure volumes and system demand** . **We are unable to predict the impact of efforts by central banks and federal,state,and local governments to combat elevated levels of inflation.If their efforts to create downward pressure on inflation are too aggressive,they may lead to a recession.Alternatively,if they are insufficient** ~~For~~ **or are** ~~certain risks,we do~~ not **sustained long enough** ~~maintain insurance coverage due~~ to **bring inflation to lower** ~~cost and / or availability.For example~~ , ~~we self- insure our product~~ **more acceptable levels,hospitals'** ~~liability~~ -- **ability** ~~risks,and we indemnify our~~ -- **or** ~~directors and officers~~ **willingness to spend on capital equipment may be impacted** for **a prolonged period** ~~third- party claims and do not carry insurance to cover that indemnity or the related underlying potential losses.Also,we do not carry,among other types~~ of **time** ~~coverage,earthquake insurance~~ . ~~In addition~~ **If a recession occurs** , **economies weaken** ~~in the future~~ , ~~we may not~~ **or inflationary trends** continue **,** ~~to maintain certain existing insurance coverage or~~ **our business** ~~adequate levels of coverage.Premiums for many types of insurance have increased significantly in recent years~~ and **results** ~~,depending on market conditions and our circumstances,certain types~~ of **operations could** ~~insurance,such as directors' and officers' insurance,may not~~ be ~~available in the future on acceptable terms or at all.Because we retain some portion of our insurable risks and,in some cases,we are entirely self- insured,unforeseen or catastrophic losses in excess of insurance coverage could require us to pay substantial amounts,which may have a material~~ **materially** ~~adverse~~ **adversely affected** ~~impact on our business,financial condition,or results of operations~~ .INFORMATION TECHNOLOGY SYSTEM FAILURES,CYBERATTACKS,OR DEFICIENCIES IN OUR CYBERSECURITY COULD HARM OUR BUSINESS,CUSTOMER RELATIONS,FINANCIAL CONDITION,OR RESULTS OF OPERATIONS.Our information technology systems are critical to the success of our products,help us operate effectively and efficiently,interface with customers,maintain our supply chain and manufacturing operations,maintain financial accuracy and efficiency,and help us produce our ~~Consolidated Financial Statements~~ **Annual Report on Form 10- K and our other filings with the Securities and Exchange Commission** .If we do not allocate and effectively manage the resources necessary to build and sustain the proper information technology infrastructure,we could be subject to transaction errors,processing inefficiencies,the loss of existing customers,difficulty attracting new customers,business operation disruptions,diversion of the attention of management and key information technology resources,security breaches,or the unauthorized access to,loss of,or damage to intellectual

property,confidential information,or personal information.Our information technology systems **,** and those of our third- party service providers,strategic partners,and other contractors or consultants **,** are vulnerable to attack,damage,or interruption from a variety of sources.These sources include computer viruses and malware (e.g.,ransomware),malicious code, ~~natural disasters,terrorism,war,telecommunication and electrical failures,~~ hacking,cyberattacks,phishing attacks and other social engineering schemes,employee theft or misuse,human error,fraud **,natural disasters,terrorism,war,telecommunication and electrical failures** ,denial or degradation of service attacks,sophisticated nation- state and nation- state- supported actors,or unauthorized access or use by persons inside our organization,or persons with access to systems inside our organization. **Cyberattacks and other** ~~The risk of a~~ security ~~breach~~ **breaches** or ~~a disruption~~ **disruptions** ~~has generally~~ **continue to** ~~increased~~ - **increase** in ~~number~~ **frequency** , **sophistication,and** intensity ~~,~~ and ~~sophistication~~ **are becoming increasingly difficult to detect for periods of time,especially as they relate to attacks on third- party providers or their vendors.Such attacks are often carried out by motivated and highly skilled actors,who are increasingly well- resourced** .Techniques used to compromise or sabotage systems,including the use of advanced technologies,such as machine learning or **generative** artificial intelligence **(" AI ")** ,change frequently,may originate from less regulated and remote areas of the world,may be difficult to detect,and generally are not recognized until after they are launched against a target.As a result,we may be unable to anticipate these techniques or ~~to~~ implement adequate preventative measures.If our information technology systems,or those of our critical third- party vendors,do not effectively and securely collect,store,process,and report relevant data for the operation of our business,our ability to effectively plan,forecast,and execute our business plan and comply with applicable laws and regulations could be impaired.Any such impairment could materially and adversely affect our financial condition,results of operations,and the timeliness with which we report our internal and external operating results.Our business requires us to use and store customer,employee,and business partner personal information.This may include names,addresses,phone numbers,email addresses,contact preferences,tax identification numbers,and payment account information.We have implemented,and our critical third- party vendors may implement,various controls,systems,and processes intended to secure our information technology systems and the information on it.For example,we require usernames and passwords in order to access our information technology systems and use encryption and authentication technologies to secure the transmission and storage of data.We also have programs in place to detect,contain,and respond to data security incidents,and we make ongoing improvements to our information- sharing products in order to minimize vulnerabilities,in accordance with industry and regulatory standards.However,we cannot guarantee that these measures will be effective or that attempted security breaches or disruptions would not be successful or damaging.These security measures may be compromised as a result of security breaches by unauthorized persons,employee error,malfeasance,faulty password management,or other irregularity and result in persons obtaining unauthorized access to our data or accounts.Third parties may attempt to fraudulently induce employees or customers into disclosing usernames,passwords,or other sensitive information or otherwise attempt to hack into our information technology systems to obtain personal data relating to patients or employees,our confidential or proprietary information,or confidential information we hold on behalf of third parties.In addition,with the prolific use of **AI** ~~artificial intelligence~~ technologies,there is an increased risk of unauthorized or accidental disclosure.For example,our employees,third- party service providers,strategic partners,or other contractors or consultants may input inappropriate or confidential information into an **AI** ~~artificial intelligence~~ system (in particular,a system that is managed,owned,or controlled by a third party),thereby compromising our business operations.Even if the vulnerabilities that may lead to the foregoing are identified,we may be unable to adequately investigate or remediate due to attackers increasingly using tools and techniques that are designed to circumvent controls,avoid detection,and remove or obfuscate forensic evidence.The occurrence of any of these events may cause business operation disruptions,diversion of the attention of management and key information technology resources,and possibly lead to security breaches of,or the unauthorized access to,our confidential information or other business data.If the unauthorized persons successfully hack into or interfere with our connected products or services,they may create issues with product functionality that could pose a risk of the loss of data,a risk to patient safety,and a risk of product recall or field action,which could adversely impact our business and reputation.We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely ~~,a situation that has persisted since the beginning of the COVID- 19 pandemic~~ ,which may create additional opportunities for cybercriminals to exploit vulnerabilities.As described above,we also rely on external vendors to supply and / or support certain aspects of our information technology systems.The systems of these external vendors may contain defects in design or manufacture or other problems that could unexpectedly compromise the security of our own information technology systems,and we are dependent on these third parties to deploy appropriate security programs to protect their systems.In addition to potential exposure to data breaches,security and cybersecurity incidents,or other actions that may compromise the security of or interfere with the function of our systems,defects or vulnerabilities in the software or systems of our external vendors may expose failures in our internal controls and risk management processes,which may adversely impact our business,financial condition,or results of operations and may also harm our reputation,brand,and customer relationships.While we devote significant resources to network security,data encryption,and other security measures to protect our systems and data,these security measures cannot provide absolute security.We and certain of our service providers are,from time to time,subject to cyberattacks and security breaches and incidents.We consider such cyberattacks or security breaches and incidents to be in the ordinary course of business for a company of our size in our industry.While we do not believe that we have experienced any significant system failure,accident,or security breach to date,if such an event were to occur,it could impair our ability to attract and retain customers for our products,impact the price of our stock,materially damage commercial relationships,and expose us to litigation or government investigations,which could result in penalties,fines,or judgments against us.The costs to us to eliminate or alleviate network security problems,bugs,viruses,worms,ransomware and other malicious software programs,and security vulnerabilities could be significant.Our efforts to address these problems may not be successful and could result in unexpected interruptions,delays,cessation of service,and harm to our business operations.Moreover,if a

security breach affects our systems or results in the unauthorized release of personal information,our reputation and brand could be materially damaged,and use of our products and services could decrease.We would also be exposed to a risk of loss,litigation and potential liability,and regulatory scrutiny,which could have a material adverse impact on our business,financial condition,or results of operations.Furthermore,we may implement changes to information technology systems that could have significant impacts on our manufacturing,sales,and finance functions,among other teams.These impacts may include **,but are not limited to,** (i) operational disruptions resulting from the slow adaptation of the new information technology systems by employees,whether due to inadequate training or resistance to change,or data loss during the transition to the updated information technology system,including critical customer data,or improper planning leading to the loss of essential software features needed for specific business requirements;(ii) inaccurate financial reporting due to inaccurate data transfer or technical issues;(iii) financial losses due to system failures or **cost overruns;(iv) security risks involving potential data breaches,unauthorized access,or loss of sensitive information;(v) compliance risks arising should the updated technology fail to meet regulatory requirements or industry standards;and (vi) strategic risks if the technology implementation fails to deliver the expected benefits.While we maintain cyber insurance coverage that is intended to address data security risks,such insurance coverage may be insufficient to cover all losses or claims that may arise** . IF OUR PRODUCTS DO NOT ACHIEVE AND MAINTAIN MARKET ACCEPTANCE, WE WILL NOT BE ABLE TO GENERATE THE REVENUE NECESSARY TO SUPPORT OUR BUSINESS. The da Vinci surgical **systems, Ion endoluminal** system **,** and our other products represent a ~~fundamentally new way of~~ **novel and advanced approach to** performing medical procedures. Achieving and maintaining physician, patient, and third- party payor acceptance of robotic- assisted medical procedures as a preferred method of performing these procedures is crucial to our success. If our products fail to achieve or maintain market acceptance, customers will not purchase our products, and we will not be able to generate the revenue necessary to support our business. We believe that physicians' and third- party payors' acceptance of the benefits of procedures performed using our products will be essential for acceptance of our products by patients. Physicians will not recommend the use of our products unless we can demonstrate that they produce results comparable or superior to existing techniques. Even if we can prove the effectiveness of our products through clinical studies, physicians may elect not to use our products for any number of other reasons. For example, cardiologists may continue to recommend conventional heart surgery simply because such surgery is already widely accepted. In addition, physicians may be slow to adopt our products because of the perceived liability risks arising from the use of new products and the uncertainty of reimbursement from third- party payors, particularly in light of ongoing healthcare reform initiatives and the evolving U. S. healthcare environment. **Broad use of our products requires thorough training of patient care teams on their safe and effective use.** We expect that there will continue to be a learning process involved for ~~patient~~ **such** care teams to become proficient in the use of our products ~~. Broad use of our products requires training of patient care teams~~ . Market acceptance could be delayed by the time required to complete this training. We may not be able to rapidly train patient care teams in numbers sufficient to generate adequate demand for our products. IF HOSPITALS ARE UNABLE TO OBTAIN COVERAGE AND REIMBURSEMENT FOR PROCEDURES USING OUR PRODUCTS, IF REIMBURSEMENT IS INSUFFICIENT TO COVER THE COSTS OF PURCHASING OUR PRODUCTS, OR IF LIMITATIONS ARE IMPOSED BY GOVERNMENTS ON THE AMOUNT HOSPITALS CAN CHARGE FOR CERTAIN PROCEDURES, WE MAY BE UNABLE TO GENERATE SUFFICIENT SALES TO SUPPORT OUR BUSINESS. In the U. S., hospitals generally bill for the services performed with our products to various third- party payors, such as Medicare, Medicaid, other government programs, and private insurance plans. If hospitals do not obtain sufficient reimbursement from third- party payors for procedures performed with our products, or if government and private payors' policies do not cover surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business. In addition, to the extent that there is a shift from an inpatient setting to outpatient settings, we may experience pricing pressure and a reduction in the number of procedures performed. Our success in OUS markets also depends on the eligibility of our products for coverage and reimbursement through government- sponsored healthcare payment systems and third- party payors. Reimbursement practices vary significantly by country. Many OUS markets have government- managed healthcare systems that control reimbursement for new products and procedures. Other foreign markets have both private insurance systems and government- managed systems that control reimbursement for new products and procedures. Market acceptance of our products may depend on the availability and level of coverage and reimbursement in a country within a particular time. In addition, healthcare cost containment efforts similar to those in the U. S. are prevalent in many of the other countries in which we sell, and intend to sell, our products, and these efforts are expected to continue. Refer to our risk factor titled " Changes in ~~Healthcare~~ **healthcare** ~~Legislation~~ **legislation** and ~~Policy~~ **policy** ~~May~~ **may** ~~Have~~ **have an** ~~a Material Adverse~~ **adverse** ~~Effect~~ **effect** on ~~Our~~ **our** ~~Business~~ **business** , ~~Financial~~ **financial** ~~Condition~~ **condition** , or ~~Results~~ **results** of ~~Operations~~ **operations** " for additional risks related to the ability of hospitals to obtain reimbursements. In China, since 2022, several provinces ~~,~~ ~~including the Hunan Provincial Healthcare Security Administration,~~ have implemented significant limits on what hospitals can charge patients for surgeries using robotic surgical technology, including soft tissue surgery ~~and orthopedics~~ . **To date,** ~~These~~ **these** limits have ~~significantly~~ impacted the number of procedures performed ~~and have~~ **in those provinces, which has** impacted our instruments and accessories revenue ~~in those provinces~~ . Companies providing robotic surgical technology, including our joint venture in China, have been meeting with Chinese government healthcare agencies to discuss these developments and to provide feedback. We cannot assure you that additional provincial or national healthcare agencies and administrations will not impose similar limits, and we expect to continue to face increased pricing pressure, both of which could further impact the number of procedures performed and our instruments and accessories revenue in China. IF OUR PRODUCTS CONTAIN DEFECTS OR ENCOUNTER PERFORMANCE PROBLEMS, WE MAY HAVE TO RECALL OUR PRODUCTS AND OUR REPUTATION MAY SUFFER. Our success depends on the quality and reliability of our products. While we subject components sourced and products manufactured to stringent quality specifications and processes, our products incorporate

mechanical parts, electrical components, optical components, and computer software, any of which may contain errors or exhibit failures, especially when products are first introduced. Component failures, manufacturing flaws, design defects, or inadequate disclosure of product- related risks with respect to our products could result in an unsafe condition ~~or~~ **for ,** injury to, or death of **a** ~~, the~~ patient. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex surgical procedures, due to the serious and costly consequences of product failure, we and our customers have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products. Although our products are subject to stringent quality processes and controls, we cannot provide assurance that our products will not experience component aging, errors, or performance problems. If we experience product flaws or performance problems, any or all of the following could occur: • delays in product shipments; • loss of revenue; • delay in market acceptance; • diversion of our resources; • damage to our reputation; • product recalls, including, but not be limited to, product withdrawals from the market, labeling changes, design changes, customer notifications, and notifications to global regulatory bodies; • regulatory actions; • increased service or warranty costs; or • product liability claims. Costs associated with defects or performance problems of our products could have a material adverse effect on our business, financial condition, or results of operations. WE UTILIZE DISTRIBUTORS FOR A PORTION OF OUR SALES AND SERVICE OF OUR PRODUCTS IN CERTAIN COUNTRIES, WHICH SUBJECTS US TO A NUMBER OF RISKS THAT COULD HARM OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. We have strategic relationships with **several** ~~a number of~~ key distributors for the sale and service of our products in certain countries. If these strategic relationships are terminated and not replaced, our revenues and / or ability to sell or service our products in the markets serviced by these distributors could be adversely affected. In addition, we may be named as a defendant in lawsuits against our distributors related to sales or service of our products performed by them. Refer to our risk factor titled " We are subject to litigation, investigations, and other legal proceedings relating to our products, customers, competitors, and government regulators that could materially adversely affect our financial condition, divert management' s attention, and harm our business. " Our distributors may affect our ability to effectively market our products in certain countries or regulatory jurisdictions if a distributor holds the regulatory authorization or certification in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or certification or sanctions for non-compliance. It may be difficult, expensive, and time- consuming for us to re- establish market access or regulatory compliance in such cases . PUBLIC HEALTH CRISES OR EPIDEMIC DISEASES..... all losses or claims that may arise . THE FAILURE TO ATTRACT AND RETAIN KEY PERSONNEL COULD HARM OUR ABILITY TO COMPETE, AND CHANGES IN OUR EXISTING LABOR RELATIONSHIPS COULD MATERIALLY ADVERSELY IMPACT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. We are highly dependent on the principal members of our management and scientific staff. For example, our product development plans depend, in part, on our ability to attract and retain software, mechanical, electrical, **manufacturing,** and robotics engineers. Attracting and retaining qualified personnel is critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the constrained labor market and competition for such personnel. **Furthermore, as market competition intensifies, there is an increased risk that our current or emerging competitors may attempt to hire our key personnel, which could be achieved through offers of substantial financial incentives or strategic opportunities, aiming to capitalize on their knowledge to accelerate their own product development initiatives. In addition, many of our tenured employees are retirement eligible and have significant historical knowledge or expertise that must be transferred to other employees. If we are unable to effectively safeguard our human capital or mitigate the risks associated with knowledge transfer, our business, financial condition, or results of operations could be adversely impacted, and there could be a detrimental effect on our competitive position.** Additionally, as a result of ~~the~~ **any** volatility in our stock price, certain long-term incentive benefits, such as ~~equity grants~~ **stock- based compensation** , may be viewed as having less value and, accordingly, could lead to higher attrition. Moreover, we may also encounter higher costs of labor through recruiting expenses, wage rates, retention benefits, or the potential existence of different employee / employer relationships, such as work councils and / or labor unions. Fluctuations in labor availability globally, including labor shortages and staff burnout and attrition, may also impact our ability to hire and retain personnel critical to our manufacturing, logistics, and commercial operations. The extent and duration of the impact of labor market challenges are subject to numerous factors, including the ~~remaining impact of COVID- 19,~~ availability of qualified and highly skilled persons in the markets where we operate and unemployment levels within these markets, behavioral changes, such as fully engaging employees, including those working from home or in a hybrid fashion, prevailing wage rates, health and other insurance and benefit costs, inflation, adoption of new or revised employment and labor laws and regulations or government programs, safety levels of our operations, and our reputation within the labor market. The loss of any of our qualified personnel or our inability to attract and retain qualified personnel could harm our business and our ability to compete, and related expenses could adversely affect our **business,** ~~results of operations and~~ financial condition **, or results of operations** . Moreover, if we fail to attract, motivate, or retain personnel ~~,~~ or **if we** relax our standards in order to meet the demands of our growth, our corporate culture, our ability to achieve our strategic objectives, and our compliance with obligations under our internal controls and other requirements may be harmed. We believe that a critical contributor to our success has been our corporate culture, which we believe fosters innovation, teamwork, and a focus on execution, as well as facilitates critical knowledge transfer and knowledge sharing. We could also be subject to union or council efforts to organize our employees. These organizational efforts, if successful, decrease operational flexibility and could adversely affect our operating efficiency. In addition, our response to any organizational efforts could be perceived negatively and harm our business and reputation **. PUBLIC HEALTH CRISES OR EPIDEMIC DISEASES, OR THE PERCEPTION OF THEIR EFFECTS, COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. Our global operations expose us to risks arising from public health**

crises and outbreaks of epidemic, pandemic, or contagious diseases, such as, historically, the COVID- 19 pandemic, the Ebola virus, Middle East Respiratory Syndrome (MERS), Severe Acute Respiratory Syndrome (SARS), and the H1N1 virus. These public health crises can divert medical resources and priorities toward disease treatment and adversely affect global economies and financial markets, which can negatively impact the number of procedures performed and our customers' capital expenditures. Furthermore, public health crises can cause significant business disruptions, including temporary closures of our facilities and those of our suppliers, as well as reduced access to customers due to measures like travel restrictions. These impacts can have a material adverse effect on our business, financial condition, or results of operations. For example, the COVID- 19 pandemic, which first emerged in late 2019, adversely impacted our operations, supply chains, and expenses. These impacts resulted from a number of impacts and measures, including, but not limited to, healthcare customers diverting resources and priorities towards disease treatment, hospital staffing shortages and supply chain disruptions that impaired their ability to provide patient care, and precautionary measures implemented by governments, businesses, and ourselves. Due to these factors, we experienced significant and unpredictable reductions in the demand for our products as customers delayed or cancelled planned procedures and capital expenditures. Furthermore, the COVID- 19 pandemic also caused widespread business disruptions, including travel restrictions, reduced access to our customers, and temporary closures of our facilities and those of our suppliers. For instance, California, where many of our operations and manufacturing facilities are located, implemented risk-reduction orders that limited our employees' ability to produce and move products through the supply chain. Such disruptions negatively impacted our business, financial condition, and results of operations. Similar effects may occur in the event of a resurgence of COVID- 19 or the emergence of another public health crisis. Also, any delays in elective surgeries caused by a public health crisis, outbreak of epidemic, pandemic, or contagious disease may create patient backlogs. The patients in such backlogs may or may not use our products when their surgeries are ultimately performed. In addition, public health crises and outbreaks of epidemic, pandemic, or contagious diseases can negatively impact global economies and financial markets, leading to economic slowdowns or recessions. Such conditions may reduce hospital spending, delay product demand, and increase the risk of customer payment defaults or agreement terminations due to liquidity constraints or funding issues. These factors create material uncertainties and risks to our business, financial condition, and results of operations . NEGATIVE PUBLICITY, WHETHER ACCURATE OR INACCURATE, CONCERNING OUR PRODUCTS OR OUR COMPANY COULD REDUCE MARKET ACCEPTANCE OF OUR PRODUCTS AND COULD RESULT IN DECREASED PRODUCT DEMAND AND REDUCED REVENUES. There have been reports and articles published questioning patient safety and efficacy associated with robotic- assisted surgery with the da Vinci surgical ~~system~~ **systems** , ~~its~~ **their** cost relative to other disease management methods, and the adequacy of surgeon training. Negative publicity, including statements made by public officials, whether accurate or inaccurate, concerning our products or our Company could reduce market acceptance of our products and could result in decreased product demand and a decline in revenues. In addition, significant negative publicity could result in an increased number of product liability claims, regardless of whether these claims are meritorious. The number of claims could be further increased by plaintiffs' law firms that use a wide variety of media to advertise their services and solicit clients for product liability cases against us. WE COULD BE SUBJECT TO SIGNIFICANT,UNINSURED LOSSES,WHICH MAY HAVE A MATERIAL ADVERSE IMPACT ON OUR BUSINESS,FINANCIAL CONDITION,OR RESULTS OF OPERATIONS.For certain risks,we do not maintain insurance coverage due to cost and / or availability.For example,we self- insure our product liability risks ~~,and we~~ **.We also** indemnify our directors and officers for third- party claims ~~and~~ **but** do not carry insurance **beyond basic Side A liability coverage** to cover that indemnity or the related underlying potential losses. ~~Also~~ **Furthermore** ,we do not carry,among other types of coverage,earthquake insurance.In ~~addition,in~~ the future,we may not continue to maintain certain existing insurance coverage or adequate levels of coverage.Premiums for many types of insurance have increased significantly in recent years and,depending on market conditions and our circumstances,certain types of insurance,such as directors' and officers' insurance,may not be available in the future on acceptable terms or at all.Because we retain some portion of our insurable risks and,in some cases,we are entirely self- insured,unforeseen or catastrophic losses in excess of insurance coverage could require us to pay substantial amounts,which may have a material adverse impact on our business,financial condition,or results of operations. **WE** ~~INFORMATION TECHNOLOGY SYSTEM FAILURES~~ EXPERIENCE LONG AND VARIABLE **CONTRACTING** ~~CAPITAL SALES~~ CYCLES AND SEASONALITY IN OUR BUSINESS, WHICH MAY CAUSE FLUCTUATIONS IN OUR FINANCIAL RESULTS. The **contracting** ~~sales and purchase order~~ cycle of our systems is lengthy, because the systems are major capital items and their purchase generally requires the approval of senior management of hospitals, their parent organizations, purchasing groups, and **/ or** government bodies ~~, as applicable~~ . In addition, sales to some of our customers are subject to competitive bidding or public tender processes. These approval and bidding processes can be lengthy. As a result, hospitals may delay or accelerate system purchases in conjunction with the timing of their capital budget timelines. Further, IDN groups are creating larger networks of system users with increasing purchasing power and are increasingly evaluating their robotic- assisted ~~surgery~~ programs to optimize the efficiency of surgeries **and bronchoscopies** using da Vinci surgical systems **and the Ion endoluminal system, respectively** . Further, the introduction of new products could adversely impact our ~~sales~~ **contracting** cycle as customers take additional time to assess the benefits and costs of such products. As a result, it is difficult for us to predict the length of **contracting cycles and, therefore, the exact timing of** capital sales ~~cycles and, therefore, the exact timing of capital sales~~ . Historically, **placements** ~~our sales~~ of **our** da Vinci surgical systems have tended to be heavier in the fourth quarter and lighter in the first quarter, as hospital budgets are reset. We have experienced **higher** procedure growth for a number of benign conditions, including **cholecystectomies,** hernia repairs, hysterectomies ~~, cholecystectomies, bariatrics~~ , and certain other surgeries. Many of these types of surgeries may be postponed in the short term by patients to avoid vacation periods and for other personal scheduling reasons. Patients may also accelerate procedures to take advantage of insurance

funding cut- off dates. Historically, we have experienced lower procedure volume **growth from the prior quarter** in the first and third quarters of the year and higher procedure volume **growth from the prior quarter** in the second and fourth quarters of the year. The timing of procedures and changes in procedure growth directly affect the timing of instruments and accessories and capital purchases by customers. The above factors may contribute to substantial fluctuations in our quarterly operating results. Because of these fluctuations, it is possible that, in future periods, our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. These fluctuations, among other factors, also mean that our operating results in any particular period may not be relied upon as an indication of future performance. WE OFFER ALTERNATIVE CAPITAL ACQUISITION APPROACHES AND..... condition, or result of operations. THIRD PARTIES MAY OFFER TO SELL ~~TO OUR CUSTOMERS~~ REMANUFACTURED ~~AND /~~ OR UNAUTHORIZED INSTRUMENTS AND ACCESSORIES **TO OUR CUSTOMERS** OR ~~TO~~ **PROVIDE UNAUTHORIZED** SERVICE **ON** OUR SYSTEMS, WHICH COULD ~~NEGATIVELY~~ **ADVERSELY** IMPACT SAFETY, OUR FINANCIAL RESULTS, AND OUR REPUTATION. A significant portion of our revenue is generated through our sales of instruments and accessories. Third parties have offered **,** and may continue to offer **,** customers counterfeit instruments and accessories and / or instruments and accessories that have been remanufactured and / or are unauthorized, including instruments that have been remanufactured to support the use of some of our limited- use instruments beyond their labeled useful life. As of the filing date, we are unaware that the FDA or any other regulatory agency has granted 510 (k) or equivalent market authorization for the remanufacturing of any instruments for use with a da Vinci **5, da Vinci** X **,** or da Vinci Xi surgical system, but we understand that the FDA has granted 510 (k) clearance to **two different companies for** one ~~company for a~~ remanufactured EndoWrist instrument **each** used with our da Vinci Si surgical **system. Additionally, third parties have provided, and may continue to provide, unauthorized service and maintenance on our da Vinci surgical systems and Ion endoluminal** system. While we generally do not approve the use by our customers of unauthorized and unapproved instruments and accessories that lack FDA clearance or other applicable regulatory approval or certification with **our systems or the unauthorized service or maintenance on** our systems, such activities could potentially result in reduced revenue, increased patient safety risks, and negative publicity for us if these products cause injuries and / or do not function as intended when used ~~with our systems~~ , any of which could have a material adverse effect on our business, financial condition, or results of operations. In addition, we may be subject to laws that regulate or attempt to regulate the manner in which third- party instruments and accessories or third- party service providers interact with our systems, and such laws could also negatively impact our business, financial condition, or results of operations. OUR BUSINESS IS SUBJECT TO COMPLEX AND EVOLVING LAWS AND REGULATIONS REGARDING **DATA** PRIVACY, DATA PROTECTION, **ARTIFICIAL INTELLIGENCE,** AND **RESPONSIBLE USE OF DATA** ~~OTHER MATTERS RELATING TO INFORMATION COLLECTION~~ . There are numerous **laws and regulations that require Intuitive to protect the personal data it generates, collects, shares, and processes on behalf of itself and / or its customers. In addition to U. S. federal and** state **privacy** ~~, federal, and foreign~~ laws, **there are various comprehensive** ~~regulations, decisions, and directives regarding data~~ privacy **laws across** ~~and security and the collection, storage, transmission, use, disclosure, and other~~ -- **the globe that we are or may become** ~~processing of different types of information about individuals and other data (including customer data), the scope of which is continually evolving and~~ subject to ~~differing interpretations~~ **and that impact our business whether related to customers, employees, products, clinical trials, recruitment, or product research and development** . We may be subject to significant consequences, including penalties ~~and ,~~ fines, **restrictions on processing personal information, and / or reputational harm** for ~~any~~ **a data breach or** failure to comply with such **legal requirements** ~~laws, regulations, and directives~~ . For example, **in the EU,** the GDPR ~~, which is in effect across the EEA, imposes several stringent requirements~~ ---- **requires** ~~for~~ controllers and processors of data relating to an identifiable living individual or " personal data " ~~including,~~ **to adhere to certain key principles whenever accessing** ~~for~~ - **or** ~~example, imposing strict standards when obtaining consent from individuals to process~~ **processing** ~~their~~ personal data **. The EU** ~~, requiring robust disclosures to individuals, providing individual data~~ **Data** ~~rights, imposing short timelines for~~ **Protection Authorities have been active in their commitment to enforcing the GDPR. The European** ~~data~~ **Data** ~~breach notifications~~ **Protection Board** , ~~limiting retention periods and secondary use of information, imposing certain requirements pertaining to health data~~ as well as **individual member states** ~~pseudonymized (i. e. , key- coded) data,~~ **continues to refine requirements under the GDPR** ~~regulating~~ - **resulting** ~~cross- border~~ **in increased obligations to demonstrate compliance through policies, procedures, training, transfer impact assessments, privacy notices, and audits. Among other requirements, the GDPR regulates** transfers of personal data ~~out of~~ **subject to** the **GDPR to** ~~EEA, as well as additional obligations when we contract~~ third ~~- party processors in connection with the processing of~~ **countries that have not been found to provide adequate protection to such** personal data ~~. The GDPR also includes a principle of accountability and the obligation to demonstrate compliance with the foregoing obligations through policies~~ , ~~procedures~~ **including the United States** , ~~training,~~ and ~~audits~~ **the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain** . The GDPR provides that EEA member states may **, in some circumstances,** make their own ~~further~~ laws **that are more restrictive** ~~and regulations limiting the processing of genetic, biometric, or health data, which could limit our~~ - **or** ~~ability to use~~ **prescriptive than GDPR, such as has occurred in France** and **Germany** ~~share personal data or could cause our costs to increase and harm our business and financial condition~~ . Failure to comply with the requirements of the GDPR and the applicable ~~national data protection laws of the~~ EEA member ~~states~~ - **state laws** may result in significant fines, regulatory investigations, reputational damage, orders to cease / change our data processing activities, enforcement notices, assessment notices (for a compulsory audit), and / or civil claims (including class actions). Compliance with data protection obligations imposed by **the** GDPR and EEA member state laws may be onerous and adversely affect our business, financial condition, or results of operations. ~~Further, since 2021, we have been subject to the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the obligations, monetary fines, and~~

~~enforcement regime under the GDPR; however, the relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.~~ We are ~~also~~ subject to **the** ~~evolving EEA and UK~~ privacy laws **in our direct** ~~on cookies, tracking technologies,~~ and **indirect** ~~e- marketing~~ **markets including** , ~~which continue~~ **but not limited** to ~~evolve~~ **, South Korea, Japan, Taiwan, India, Brazil, Canada,** and **the UK** ~~which regulators actively enforce~~ . In the United States, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, **or HIPAA,** imposes privacy, security, and breach notification obligations on ~~certain healthcare providers, health plans, and healthcare clearinghouses, known as~~ covered entities **and** ~~, as well as~~ their business associates **to ensure the confidentiality** ~~that perform certain services that involve creating~~ , ~~receiving~~ **integrity** , **and availability of** ~~maintaining, or transmitting~~ individually identifiable health information ~~for or on behalf of such covered entities and their covered subcontractors~~ . Entities that are found to be in violation of HIPAA, as ~~the~~ **a** result of a breach of unsecured ~~personal~~ **protected health** information, a complaint about privacy practices, or an audit by the U. S. Department of Health and Human Services (" HHS "), may be subject to significant civil, criminal, and administrative fines and penalties and / or additional reporting and oversight obligations if they are required to enter into a resolution agreement and corrective action plan with HHS ~~to~~ **through** ~~settle~~ **settlement agreements** ~~allegations of HIPAA non- compliance~~ . ~~Even~~ **Further, in the U. S.,** when HIPAA does not apply, according to the Federal Trade Commission (the " FTC "), violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair and / or deceptive acts or practices in violation of Section 5 (a) of the FTC Act. The FTC has **the** authority to initiate enforcement actions against entities that make deceptive statements about privacy and data sharing in privacy policies, fail to limit third- party use of personal health information, fail to implement policies to protect personal health information, or engage in other unfair practices that harm customers or that may violate Section 5 (a) of the FTC Act. The FTC expects a company' s data security measures to be reasonable and appropriate in ~~light of~~ **proportion to** 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. Additionally, federal and state consumer protection laws are increasingly being applied by the FTC and states' attorneys general to regulate the collection, use, storage, and disclosure of personal ~~or personally identifiable~~ information, through websites or otherwise, and to regulate the presentation of website content. ~~Further~~ **At the state level, multiple states have comprehensive consumer privacy laws enacted. Notably** , the California Consumer Privacy Act, as amended by the California Privacy Rights Act (~~the~~ " CCPA ") gives California residents expanded rights to access, correct, 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 ~~imposes compliance burdens on many organizations doing business in California that collect personal information about California residents. The CCPA' s definition of personal information is very broad and specifically includes biometric information (though information subject to HIPAA is expressly exempted). The CCPA~~ allows for significant fines by the ~~state~~ **California** attorney general ~~,~~ as well as a private right of action from individuals in relation to certain security breaches. ~~The enactment of the CCPA has prompted a wave of similar~~ **Similar** ~~legislative developments~~ **laws have passed** in other ~~U. S.~~ states ~~, such as Virginia, Colorado, Connecticut,~~ and ~~Utah, and~~ **are continuing to be proposed** at the **state and** federal level, reflecting ~~a~~ **the continuing** trend toward more stringent privacy legislation in the U. S. These developments are increasing our compliance ~~burden~~ **obligations** and ~~our~~ risk, including risks of regulatory fines, litigation, and associated reputational harm ~~. In addition, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the EEA or UK to third countries, including the United States. Case law from the Court of Justice of the European Union (the " CJEU ") states that the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism and potential alternative to the Privacy Shield) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case- by- case basis. On October 7, 2022, President Biden signed an Executive Order on ' Enhancing Safeguards for United States Intelligence Activities,' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU- US Data Privacy Framework (" DPF "), as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as an EU GDPR transfer mechanism to U. S. entities self- certified under the DPF. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U. S. entities self- certified under the UK Extension to the DPF. However, we expect the existing legal complexity and uncertainty regarding international persona data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged. We rely on a mixture of mechanisms to transfer personal data from our EU business to the U. S. and are evaluating whether additional mechanisms will be required to establish adequate safeguards for personal data. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used and / or start taking enforcement action, we could suffer additional costs, complaints, and / or regulatory investigations or fines. As the regulatory guidance and enforcement landscape in relation to data transfers continues to develop, we could suffer additional costs, complaints, and / or regulatory investigations or fines, and we may have to stop using certain tools and vendors. Moreover, if we are unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services. These operational changes could adversely affect our business, financial condition, or results of operations~~ . In China, we are also subject to various aspects of the country'

s data compliance regime, ~~which can include~~ **including** the Cybersecurity Law, the Data Security Law, and the Personal Information Protection Law (" PIPL "). In addition **to national laws** , ~~the relevant~~ **regulatory departments, provincial and municipal** ~~government~~ **governments , and Free Trade Zones** ~~authorities of China promulgated several regulations or released a number of draft regulations for public comment that~~ are ~~designed~~ **left** to **identify " important data, "** ~~provide further implemental guidance in accordance with these~~ -- **the definitions of which may** ~~laws. We cannot predict what~~ impact ~~the new laws and regulations or~~ **our reporting** ~~the increased costs of compliance~~ , ~~if any, will have on our operations in China, in particular the Data Security Law or PIPL, due to their recent enactment and the limited guidance available. It is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities, as these laws are drafted broadly and, thus, leave great discretion to the relevant government authorities to exercise. In Israel, The Protection of Privacy Law, 5741- 1981 (the " Israeli Privacy Law ") regulates the protection of privacy and personal data, along with several other specific regulations enacted thereunder and, in particular, the Privacy Protection Regulations (Data Security), 5777- 2017 (together with Israeli Protection of Privacy Law, the " Israeli Privacy Law and Regulations "). Under the Israeli Privacy Law and Regulations, organizations are subject to various privacy and~~ data protection **, and data transfer obligations. Draft guidelines related to medical device and** ~~requirements~~ - - **equipment data from the State Administration for Market Regulation and other unpublished rules and guidelines from other regulatory departments may impact Onsite data collection and transfers. With the possibility of more stringent medical data transfer rules in China** , **customers' appetite for our digital products** including **Onsite** ~~mandatory registration of databases with the Israeli Registrar of Databases (if certain conditions are met)~~ , **Telepresence** ~~executing data processing agreements with data recipients~~ , ~~safeguarding the collection~~ and **Case Insights may become impacted in** ~~processing of personal data, safeguarding the transfer of personal data (which is specifically subject to the requirements of the Privacy Protection Regulations), personal data breach notification obligations, and other~~ -- **the** ~~requirements~~ **future** . **Any** ~~The Privacy Protection Authority (the " PPA ") is responsible for enforcement of the Israeli Privacy Law and Regulations and periodically publishes opinions and guidelines on privacy matters. In terms of enforcement, failure to comply with the Israeli Privacy Law and Regulations can result in PPA investigations, administrative fines or sanctions, and civil or criminal actions (civil proceedings may include statutory damages without the need to prove actual damages). Furthermore, any~~ failure, or perceived failure, by us to comply with or make effective modifications to our policies or to comply with any federal, state, or international privacy, data- retention, or data- protection- related laws, regulations, orders, or industry self- regulatory principles could result in proceedings or actions against us by governmental entities or others, a loss of customer confidence, damage to our brand and reputation, and a loss of customers, any of which could have an adverse effect on our business. In addition, various federal, state, and foreign legislative or regulatory bodies may enact new or additional laws and regulations concerning privacy, data- retention, and data- protection issues, including laws or regulations mandating disclosure to domestic or international law enforcement bodies, which could adversely impact our business or our reputation with customers. For example, some countries have adopted laws mandating that some personal information regarding customers in their country be maintained solely in their country. Having to maintain local data centers and redesign ~~product~~ **products** , ~~service~~ **services** , and business operations to limit personal information processing to within individual countries could increase our operating costs significantly. ~~operational complexity.~~ Moreover,some of the AI features of our products involve,or may involve,the processing of personal data and may be subject to laws,policies,legal obligations,and codes of conduct related to privacy and data protection,each of which may be interpreted in ways that may affect the way in which we engage with machine learning and require us to make changes to our business practices and products to comply with such obligations.Our use of AI technologies may involve the storage and transmission of confidential or sensitive information,including personal information of employees,customers,and others,as well as protected health information of clients' patients.In addition,due to the sensitive nature of the information,the security features of our computers and systems,network,and communications systems infrastructure are critical to the success of **our business.** ONGOING AND ~~POTENTIAL~~ FUTURE GLOBAL CONFLICTS COULD ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. In February 2022, **armed conflict escalated between** ~~Russian~~ - **Russia and** ~~military forces launched a military action in~~ Ukraine ~~, and sustained conflict and disruption in the region has continued~~ . Russia' s military actions against Ukraine have ~~led to~~ **resulted in** substantial expansion of sanction programs imposed by the United States, the European Union ~~, the United Kingdom, 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 ~~, including, among others: • blocking sanctions against some of the largest state- owned and private Russian financial institutions (and their subsequent removal from the Society for Worldwide Interbank Financial Telecommunication payment system) and certain Russian businesses, some of which have significant financial and trade ties to the European Union; • blocking sanctions against Russian and Belarusian individuals, including the Russian President, other politicians, and those with government connections or involved in Russian military activities; and • blocking of Russia' s foreign currency reserves as well as expansion of sectoral sanctions and export and trade restrictions, limitations on investments and access to capital markets, and bans on various Russian imports~~ . In **response** ~~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~~ - **export controls** ~~of various products~~ , and ~~imposed~~ other economic and financial restrictions. **Related** ~~The situation is rapidly evolving, and additional~~ sanctions **, export controls, or other actions that may be initiated** by **countries including the U. S., the European Union, or** Russia ~~on the one hand~~ **(e. g.** , **potential cyberattacks** ~~and by the other countries on the other hand~~ , **disruption of energy flows, etc.)** 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, financial condition **and liquidity** , or results of operations. ~~Separately~~ **Additionally** , ~~on~~

in October ~~7,~~ 2023, ~~Hamas, a U. S.- designated terrorist organization, launched a series of coordinated attacks from the Gaza Strip onto Israel. On October 8, 2023, Israel formally declared war on Hamas, and the~~ armed conflict **escalated between Israel and Hamas** ~~is ongoing as of the date of this filing~~ . Hostilities between Israel and Hamas could **persist,** escalate ~~and~~ **, or expand to** involve ~~surrounding~~ **more** countries **and regions** in the Middle East ~~. Furthermore, following Hamas' attack on Israel, the Houthi movement, which controls parts of Yemen, launched a number of attacks on marine vessels in the Red Sea. The Red Sea is an important maritime route for international trade~~ . As a result of such disruptions, we may experience in the future extended lead times, delays in supplier deliveries, and increased freight costs. The risk of ongoing supply disruptions may further result in delayed deliveries of our products. We are actively monitoring the situation in Ukraine and Russia and the conflict between Israel and Hamas and assessing the impacts on our business, including our business partners and customers. To date, we have not experienced any material interruptions in our infrastructure, supplies, technology systems, or networks needed to support our operations. We **cannot** ~~have no way to~~ predict the progress, outcome, or consequences of the military ~~conflict~~ **conflicts** in Ukraine **and** ~~or its impacts in Ukraine, Russia, Belarus, Europe, or the U. S., or of the conflict in~~ the Israel- Gaza regions **or** ~~and any potential increases in hostilities in the~~ **their** ~~Middle East~~ **impacts on the global economy** . The length, impact, and outcome of ongoing military conflicts is highly unpredictable and could 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 **global shipping expenses, greater volatility in foreign exchange and interest rates, an increase in** cyberattacks and espionage **, and other unforeseen business disruptions** . The extent and duration of the military action, sanctions, other consequences, such as 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. Impacts to our business may include, but are not limited to, **a reduction in** procedures performed, **reduced** demand for our products, ~~and~~ **limitations on hospitals'** ability to spend on capital equipment and **in** healthcare **spending** in general **, and supply disruption** . Any such disruption may also magnify the impact of other risks described **in this " Risk Factors " section** . INCORPORATING ARTIFICIAL INTELLIGENCE **TECHNOLOGIES** INTO OUR PRODUCTS, SERVICES, AND OPERATIONS MAY RESULT IN LEGAL AND REGULATORY RISKS OR ~~REPUTATIONAL HARM OR~~ HAVE OTHER ADVERSE CONSEQUENCES TO OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. Our current operations, products, and services use ~~artificial intelligence (" AI~~ **technologies** ~~")~~ , including machine learning. Examples of our current uses of machine learning include (i) using algorithms to process video and ~~system~~ **machine** data to identify surgical activities and surgical ~~performance~~ indicators to support learning, teaching, and practice management, and (ii) using algorithms to support surgical planning and navigation. Future innovations in our products and services will likely continue to incorporate AI, and these applications may become important in our operations over time, for example, our development of machine learning- enabled medical devices (" MLMDs "). As with many technological innovations, there are significant risks and challenges involved in maintaining and deploying these technologies, and there can be no assurance that the usage of such technologies will enhance our products or services or be beneficial to our business, including our efficiency or profitability. Our ability to continue to maintain or use such technologies may be dependent on access to specific third- party software and infrastructure, such as processing hardware, and we cannot control the availability or pricing of such third- party software and infrastructure, especially in a highly competitive environment. Our products and services may not compete effectively with alternative products and services if we are not able to source and integrate the latest technologies into our products and services. In addition, **several** ~~a number of~~ aspects of intellectual property protection in the field of AI are currently under development, and there is uncertainty and ongoing litigation in different jurisdictions as to the degree and extent of protection warranted for AI technologies and relevant system input and outputs. If we fail to obtain protection for the intellectual property rights concerning our AI technologies, or later have our intellectual property rights invalidated or otherwise diminished, our competitors may be able to take advantage of our research and development efforts to develop competing products, which could adversely affect our business, reputation, financial condition, or results of operations. Refer to our risk factor titled " If we are unable to fully protect and successfully defend our intellectual property from use by third parties, our ability to compete in the market may be harmed " for additional risks related to intellectual property. The regulatory landscape surrounding AI is also evolving, and the use of machine learning technologies may expose us to an increased risk of regulatory enforcement and litigation. **As** ~~For example, in October 2023,~~ the FDA ~~, Health Canada,~~ and ~~the~~ **other regulatory authorities continue to develop** ~~U. K.' s Medicines~~ and ~~Healthcare~~ **incorporate such principles into their regulation of machine learning medical devices, it is possible that medical** products **using AI and** ~~Regulatory Agency jointly published the " Predetermined Change Control Plans for Machine~~ **machine** ~~Learning~~ **learning will become subject to** ~~- Enabled Medical Devices: Guiding Principles. " These principles may require~~ significant ~~regulatory~~ **additional** oversight, ~~such as additional~~ **including with respect to** premarket review, **modification,** ~~and ongoing regulation through~~ monitoring, maintenance, and ~~improving~~ device performance ~~to ensure safety and effectiveness~~ . In the U. S., an executive order was issued in October 2023 on the Safe, Secure and Trustworthy Development and Use of AI, emphasizing the need for transparency, accountability, and fairness in the development and use of AI, including in the healthcare industry. The order seeks to balance fostering innovation with addressing risks associated with AI by providing eight guiding principles and priorities, such as ensuring that consumers are protected from fraud, discrimination, and privacy risks related to AI. The order also calls for future regulations from various agencies, such as the Department of Commerce (to draft guidance for detecting and authenticating AI content) and the Federal Trade Commission (to ensure fair competition and reduce consumer harm). In alignment with the order, other agencies have published guidance. **Agencies such as the Department of Commerce and the Federal Trade Commission have also issued proposed rules governing the use and development of AI technologies. Further, legislation related to AI technologies has been introduced at the federal level and is advancing at**

the state level. For example, on March 13, 2024, Utah passed the Utah AI Policy Act, which took effect in May 2024, imposing certain disclosure requirements on the use of AI and, on May 17, 2024, Colorado enacted the Colorado AI Act, which will take effect in February 2026. Further, the California Privacy Protection Agency is currently in the process of finalizing regulations under the CCPA regarding the use of automated decision- making. Such additional regulations may impact our ability to develop, use, and commercialize AI technologies in the future. Apart from the U. S., policymakers in key jurisdictions, such as the EU, are actively working on legislation and regulations to encourage the development and use of ethical and safe AI technologies. For example, on ~~April~~ **May** 21, ~~2021~~ **2024** , the European ~~Commission proposed a regulation seeking to~~ **Union legislators approved the EU Artificial Intelligence Act (" EU AI Act "), which** ~~establish~~ **establishes** a comprehensive, risk- based governance framework for AI in the EU market ~~(~~**". The** EU AI Act ~~")~~ **enters into force on August 2, 2024, and the majority of the substantive requirements will apply from August 2, 2026** . The ~~proposal is intended to~~ **EU AI Act will** apply to companies that develop, use, and / or provide AI in the EU and includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security, ~~and~~ accuracy **, general purpose AI, and foundation models, and proposes fines for breach of up to 7 % of worldwide annual turnover** . In addition, on September 28, 2022, the European Commission proposed two **Liability** Directives seeking to establish a harmonized civil liability regime for AI in the EU **in order to facilitate civil claims in respect of harm caused by AI and to include AI- enabled products within the scope of the EU' s existing strict product liability regime** . These **Liability Directives were published in** ~~regulatory proposals are at varying stages of~~ the **Official Journal of** ~~legislative process and are not yet finalized;~~ the **EU on July 12, 2024, and entered into force on August 1, 2024. The** EU AI Act ~~is at an~~ **and** ~~advanced stage and~~ the **Liability Directives will** ~~text is currently expected to be finalized by the end of 2023. Once finalized and in force, this regulatory framework is expected to~~ have a material impact on the way ~~that~~ AI is regulated in the EU **. Recent case law from the CJEU has also taken** ~~and~~ **an expansive view of the scope of the GDPR' s requirements around automated decision- making and introduced uncertainty in the interpretation of these rules. The EU AI Act and developing interpretation and application of the GDPR in respect of automated decision- making** , together with developing guidance and / or decisions in this area, may affect our use of AI **technologies** and our ability to provide, improve, or commercialize our ~~services~~ **business** , require additional compliance measures and changes to our operations and processes, result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, ~~operations, and~~ financial condition **, or results of operations** . Other jurisdictions where we operate have already or are also expected to introduce guidelines and regulations around the use of AI within the next few years. The regulations may impose onerous obligations and may require us to rework or reevaluate improvements to be compliant, potentially increasing costs. Moreover, some of the AI features..... to the success of our business. A breach or failure in our security measures could occur from a variety of circumstances and events, including third- party action, employee negligence or error, malfeasance, computer viruses, **cyberattacks** ~~cyber- attacks~~ , or ransom- related attacks by computer hackers, failures during the process of upgrading or replacing software and databases, power outages, hardware failures, telecommunication failures, user errors, or catastrophic events, and any of the foregoing events could have a material adverse effect on our business, financial condition, or results of operations. For more information on risks associated with the processing of confidential and sensitive information, including personal information, refer to our risk factor titled " Information technology system failures, cyberattacks, or deficiencies in our cybersecurity could harm our business, customer relations, financial condition, or results of operations. " Though we have taken steps to be thoughtful in our development, training, and implementation of machine learning, including taking steps to comply with the laws and frameworks discussed above that are currently in effect, our machine learning- related processing could pose certain risks to our customers, including patients, clinicians, and healthcare institutions, and it is not guaranteed that regulators will agree with our approach to limiting these risks or to our compliance more generally. Risks can include, but are not limited to, the potential for errors or inaccuracies in the algorithms or models used by the MLMDs, the potential for bias or inaccuracies in the data used to train the MLMDs, the potential for improper processing of personal information that could lead to deprecation of our algorithms, and the potential for cybersecurity breaches that could compromise patient data or device functionality. Such risks could negatively affect the performance of our products, services, and business, as well as our reputation and the reputations of our customers, and we could incur liability through the violation of laws or contracts to which we are a party or civil claims .DISRUPTIONS AT THE FDA AND OTHER GOVERNMENT AGENCIES OR NOTIFIED BODIES COULD HINDER THEIR ABILITY TO HIRE,RETAIN,OR DEPLOY PERSONNEL,OR OTHERWISE PREVENT PRODUCTS FROM BEING DEVELOPED,CLEARED,CERTIFIED,APPROVED,OR COMMERCIALIZED IN A TIMELY MANNER OR AT ALL,WHICH MAY ADVERSELY AFFECT OUR BUSINESS,FINANCIAL CONDITION,OR RESULTS OF OPERATIONS.Hospitals,health systems,and physicians depend on a number of government agencies and services to effectively deliver healthcare to their patients.A prolonged government shutdown could impact inspections,regulatory review and certifications,grants,or approvals or could cause other situations that could impede their ability to effectively deliver healthcare,including attempts to reduce payments and other reimbursements to hospitals by federal healthcare programs.These situations could adversely affect our customers' ability to perform procedures with our devices and / or their decisions to purchase additional products from us.In addition,the ability of the FDA,foreign authorities,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, **the** ability to hire and retain key personnel and accept the payment of user fees,and statutory,regulatory,and policy changes.In addition,government funding of other government agencies that fund research and development activities is subject to the political process,which is inherently fluid and unpredictable.Disruptions at the FDA and other agencies or notified bodies,including a prolonged government shutdown,may cause significant regulatory delays and,therefore,delay our efforts to seek clearances,approvals,or certifications from the FDA,foreign authorities,and notified bodies and adversely affect business travel and **the** import and export of products,all of which could have a material adverse effect on our business,financial

condition,or results of operations.For example,over the last several years,the U.S.government has shut down several times,and certain regulatory agencies,such as the FDA,have had to furlough critical FDA employees and stop critical activities. ~~Separately~~ **If a prolonged government shutdown occurs,or if global health concerns 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.For example** ,in response to the ~~global~~ COVID- 19 pandemic **that began in 2019** ,the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. ~~Even though~~ **Separately,in the EU,** ~~the~~ **their designation process experienced considerable** ~~FDA has since resumed standard inspection operations of domestic facilities where feasible,any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative~~ delays **during** ~~.If a prolonged government shutdown occurs,or if global health concerns prevent the FDA,other~~ -- **the COVID- 19 pandemic** ~~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** ~~For instance,in~~ the EU,notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. ~~Their designation process,which is significantly stricter under the new regulation,has experienced considerable delays due to the COVID- 19 pandemic.~~ Despite **the** ~~a recent~~ increase in designations,the current number of notified bodies designated under the ~~new~~ **EU Medical Devices** Regulation remains significantly lower than the number of notified bodies designated under the previous regime **.The current designated notified bodies are,therefore,facing a backlog of requests,and review times have lengthened.This situation could impact our ability to grow our business in the EU and EEA** . WE MAY INCUR LOSSES ASSOCIATED WITH CURRENCY FLUCTUATIONS AND MAY NOT BE ABLE TO EFFECTIVELY HEDGE OUR EXPOSURE. Our operating results are subject to volatility due to fluctuations in foreign currency exchange rates. Our primary exposure to fluctuations in foreign currency exchange rates relates to revenue and operating expenses denominated in currencies other than the U. S. dollar. The weakening of foreign currencies relative to the U. S. dollar adversely affects our foreign currency- denominated revenue. **Gross profit** ~~Margins~~ **margins** on ~~OUS~~ **foreign currency- denominated** revenue could also be materially adversely affected by foreign currency exchange rate fluctuations, as we may not be able to raise local prices to fully offset the strengthening of the U. S. dollar. Conversely, the strengthening of foreign currencies relative to the U. S. dollar, while generally beneficial to our foreign currency- denominated revenue and earnings, may cause us to reduce pricing on our products in ~~our OUS~~ markets **that are not priced in U. S. dollars** and may cause us to incur losses on our foreign currency hedging instruments, thereby limiting the benefit that strengthened foreign currencies could have on our results of operations. We attempt to mitigate a portion of these risks through foreign currency hedging, based on our judgment of the appropriate trade- offs among risk, opportunity, and expense. Although we have established a hedging program to partially hedge our exposure to foreign currency exchange rate fluctuations, primarily related to transactions denominated in the Euro, the British Pound, the Japanese Yen, the Korean Won, the New Taiwan Dollar, and the Swiss Franc, and we regularly review our hedging program and make adjustments as necessary, our hedging activities may not offset **all** ~~more than a portion~~ of the adverse financial impact caused by unfavorable movement in foreign currency exchange rates, which could materially adversely affect our financial condition or results of operations. See " Item 7A. Quantitative and Qualitative Disclosures About Market Risk " for additional discussion on the impact of foreign exchange risk. IF WE DO NOT SUCCESSFULLY MANAGE OUR COLLABORATION, LICENSING, JOINT VENTURE, STRATEGIC ALLIANCE, OR PARTNERSHIP ARRANGEMENTS WITH THIRD PARTIES, WE MAY NOT REALIZE THE EXPECTED BENEFITS FROM SUCH ARRANGEMENTS, WHICH MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. From time to time, we enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances, or partnerships to complement or augment our research and development, product development, training, procedure development, ~~and~~ marketing **, and commercialization** efforts. For example, in 2016, we entered into an agreement to form the Joint Venture. In ~~January~~ 2019, the Joint Venture acquired certain assets related to the da Vinci distribution business of Chindex, a subsidiary of **Shanghai Fosun Pharmaceutical (Group) Co. Ltd. ("** Fosun Pharma **")** , following which the Joint Venture began direct distribution operations for da Vinci **surgical system** products and services in China. There can be no assurance that we and the Joint Venture can successfully complete development of robotic- assisted ~~, catheter- based~~ medical devices ~~,~~ or that we and the Joint Venture will successfully commercialize such products. There can also be no assurance that the Joint Venture will not require additional contributions to fund its business, that the Joint Venture will ~~become~~ **remain** profitable, or that the expected benefits of the acquisition of certain assets of Chindex will be realized. Proposing, negotiating, and implementing collaborations, in- licensing agreements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. In addition, other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. As a result, we may not identify, secure, or complete any such arrangements in a timely manner, on a cost- effective basis, or on otherwise favorable terms, if it all. There can be no assurance that we will realize the expected benefits from these alliances. In addition, we may not be in a position to exercise sole decision- making authority regarding any collaboration or other arrangement, which could create the potential risk of creating impasses on decisions, and our alliances may have economic or business interests that are, or that may become, inconsistent with our interests. It is possible that conflicts may arise in these relationships, such as conflicts concerning the achievement of performance milestones or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights, or the ownership or control of intellectual property developed during the collaboration. These alliances can be difficult to manage, given the potentially different interests of the parties involved, and we could suffer delays in product development or other operational difficulties ~~. There can be no assurance that we will realize a return on our strategic~~

~~investments. Further, if we acquire privately held companies, valuations of such companies are inherently complex due to the lack of readily available market data. If we determine that our investments in privately held companies have experienced a decline in value, we may be required to record impairments, which could be material and have an adverse effect on our results of operations~~ . These alliances may also involve significant costs and divert the focus and attention of our management and other key personnel. Any of these relationships may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, or disrupt our ordinary business activities. Such arrangements may also expose us to numerous known and unknown risks, including unique risks with respect to the economic, political, and regulatory environment of any foreign entities with whom we partner, including Fosun Pharma. Any of the foregoing may have a material adverse effect on our business, financial condition, or results of operations. IF WE FAIL TO SUCCESSFULLY ACQUIRE OR INTEGRATE NEW BUSINESSES, PRODUCTS, AND TECHNOLOGY, WE MAY NOT REALIZE EXPECTED BENEFITS, OR OUR BUSINESS MAY BE HARMED. We need to grow our ~~businesses~~ -- **business** in response to changing technologies, customer demands, and competitive pressures. In some circumstances, we may decide to grow our business through the acquisition of complementary businesses, products, or technologies rather than through internal development. Identifying suitable acquisition candidates can be difficult, time- consuming, and costly, and we may not be able to identify ~~suitable~~ **appropriate** candidates or successfully complete identified acquisitions. In addition, completing an acquisition can divert our management and key personnel from our business operations, which could harm our business and affect our financial results. Even if we complete an acquisition, we may not be able to successfully integrate newly acquired organizations, products, technologies, or employees into our operations or may not fully realize some of the expected synergies. An acquired company may have deficiencies in product quality, regulatory marketing authorizations or certifications, or intellectual property protections, which are not detected during due diligence activities or ~~which~~ are unasserted at the time of acquisition. It may be difficult, expensive, and time- consuming for us to re- establish market access, regulatory compliance, or cure such deficiencies in product quality or intellectual property protection in such cases, which may have a material adverse impact on our business, financial condition, or results of operations. Integrating an acquisition can also be expensive and time- consuming and may strain our resources. In many instances, integrating a new business will also involve implementing or improving internal controls appropriate for a public company at a business that lacks them. In addition, we may be unable to retain the employees of acquired companies or the acquired company' s customers, suppliers, distributors, or other partners for a variety of reasons, including that these entities may be our competitors or may have close relationships with our competitors. Furthermore, acquired companies may have less mature or less sophisticated information **technology** systems, securities practices, or training, which may result in an increased risk of security and cybersecurity incidents when such companies are integrated. For example, in 2020, we acquired Orpheus Medical Ltd. and its wholly owned subsidiaries (" Orpheus Medical ") to deepen and expand our integrated informatics platform. The integration of this acquisition involved complex operations across different geographic locations and new products, distribution networks, and legal jurisdictions. Failure to successfully integrate our acquisitions may have a material adverse impact on our business, financial condition, or results of operations. WE ARE EXPOSED TO CREDIT RISK AND FLUCTUATIONS IN THE MARKET VALUE OF OUR INVESTMENTS. Our investment portfolio includes both domestic and international investments. The credit ratings and pricing of our investments can be negatively affected by liquidity concerns, credit deterioration, financial results, economic risk, political risk, or other factors. As a result, the value and liquidity of our cash equivalents and marketable securities could fluctuate substantially. Our other income and expense could also vary materially from expectations depending on gains or losses realized on the sale or exchange of investments, impairment charges resulting from revaluations of debt and equity securities and other investments, changes in interest rates, increases or decreases in cash balances, volatility in foreign exchange rates, and changes in the fair value of derivative instruments. Increased volatility in the financial markets and overall economic uncertainty could increase the risk that actual amounts realized on our investments may differ significantly from the fair values currently assigned to them. The value of our investments may also decline due to instability in the global financial markets, which may reduce the liquidity of securities included in our portfolio. ~~The~~ **For example, the** closure of SVB and other institutions swept into receivership and the appointment of the FDIC as receiver in 2023 created bank- specific and broader financial institution liquidity risk and concerns. ~~Although~~ **We maintain** the **majority of our cash and cash equivalents in accounts with major** U. S. ~~Department of the Treasury, the Federal Reserve,~~ and ~~the FDIC jointly released a statement that~~ **multi- national financial institutions, and our** ~~depositors~~ -- **deposits exceed** ~~at SVB and other banks that have been similarly swept into receivership would have access to their funds, even those in excess of the standard FDIC insurance~~ --- **insured** limits **.** ~~, under a systemic risk exception, future~~ **Future** adverse developments with respect to ~~specific~~ **these** financial institutions or the broader financial services industry may impair our ability to access capital needed to support near- term working capital needs, whether from our existing investment and deposit accounts and credit facilities or otherwise, and may lead to market- wide liquidity shortages and create additional market and economic uncertainty. Any decline in available funding or access to our cash and liquidity resources could also result in breaches of our financial and / or contractual obligations. Our **two** Intuitive Ventures ~~fund~~ **funds** ~~invests~~ -- **invest** in early- stage companies, which involve substantial risks and uncertainties. These risks and uncertainties include, among other things, uncertainties inherent in research and development; uncertainties regarding the ability of Intuitive Ventures to identify investment candidates; uncertainties regarding the success of Intuitive Ventures' investments; uncertainties and variables inherent in the operating and financial performance in investments made, including, among other things, competitive developments and general economic, political, business, industry, regulatory and market conditions; future exchange and interest rates; and changes in tax and other laws, regulations, rates and policies **. There can be no assurance that we will realize a positive return on our strategic investments. Further, if we invest in privately held companies, valuations of such companies are inherently complex due to the lack of readily available market data. If we determine that our investments in privately held companies have experienced a decline in value, we may be required to record impairments, which could be material and have an adverse**

effect on our results of operations . While we have not realized any significant losses on our cash equivalents, marketable securities, or other investments, future fluctuations in their value could have a material adverse impact on our business, financial condition, or results of operations. CHANGES IN OUR EFFECTIVE TAX RATE MAY ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. We are subject to taxes in the U. S. and other jurisdictions around the world. Tax rates in these jurisdictions may be subject to significant change due to economic and / or political conditions. A number of other factors may also impact our future effective tax rate, including: • the jurisdictions in which profits are determined to be earned and taxed; • the resolution of issues arising from tax audits with various tax authorities; • changes in the valuation of our deferred tax assets and liabilities; • increases in expenses not deductible for tax purposes, including write- offs of acquired intangibles and impairment of goodwill in connection with acquisitions; • changes in the availability of tax credits, tax holidays, and tax deductions; • changes in share- based compensation; • changes in tax laws or the interpretation of such tax laws; and • changes in generally accepted accounting principles. We are unable to predict what changes to the tax laws of the U. S. and other jurisdictions may be ~~proposed or~~ enacted in the future or what effect such changes would have on our business, including **tax law** changes resulting from the base erosion and profit shifting (" BEPS ") project **and the Two Pillar Solution** undertaken by the Organization for Economic Co- operation and Development (" OECD ") ~~. As part of the OECD' s BEPS project, over 140 member jurisdictions of the OECD Inclusive Framework have joined the Two- Pillar Solution to Address the Tax Challenges of the Digitalization of the Economy~~ , which includes ~~a reallocation of taxing rights among jurisdictions and~~ a global minimum tax rate ~~of 15 %~~ . **Various** ~~On December 15, 2022, the Council of the European Union approved its directive to implement rules regarding such a 15 % global minimum tax rate. Other~~ countries have adopted, or have announced plans to adopt, new tax laws to align with the global minimum tax. These changes could increase tax uncertainty and may adversely impact our provision for income taxes. Any significant increase in our future effective tax rate could have a material adverse impact on our business, financial condition, or results of operations . DISRUPTIONS AT THE FDA AND OTHER..... our business in the EU and EEA . WE ARE SUBJECT TO RISKS ASSOCIATED WITH REAL ESTATE CONSTRUCTION AND DEVELOPMENT. The development of our facilities is subject to risks relating to our ability to complete our projects on schedule or within budget. Factors that may result in a development project being prevented or delayed from completion or exceeding budget include, but are not limited to (i) construction delays due to labor challenges, poor weather, defects, or cost overruns, which may increase project development costs; (ii) cost escalations associated with materials, including changes in availability, proximity, and cost of materials, such as steel, cement, concrete, aggregates, oil, fuel, and other construction materials, including potential risks arising from geopolitical conflicts, changes in U. S. trade policies and retaliatory responses from other countries, changes in foreign exchange rates, as well as cost escalations associated with subcontractors and labor; (iii) the discovery of hazardous or toxic substances, or other environmental, culturally- sensitive, or related issues; (iv) an inability to obtain, or a significant delay in obtaining, zoning, construction, occupancy, and other required governmental permits and authorizations; (v) difficulty in complying with local, city, county, and state rules and regulations regarding permitting, zoning, subdivision, utilities, and water quality, as well as federal rules and regulations regarding air and water quality and protection of endangered species and their habitats; (vi) insufficient infrastructure ~~capacity or availability~~ (e. g., water, sewer, and roads) **capacity or availability** to serve the needs of our projects; (vii) failure to achieve or sustain anticipated occupancy levels; (viii) condemnation of all or parts of development or operating properties, which could adversely affect the value or viability of such projects; and (ix) natural disasters and other extreme weather conditions, including, but not limited to, hurricanes, tornadoes, earthquakes, wildfires, or flooding. CLIMATE CHANGE, NATURAL DISASTERS, OR OTHER EVENTS BEYOND OUR CONTROL COULD DISRUPT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. Natural disasters, terrorist activities, and other events beyond our control including, but not limited to, internet security threats and violence motivated by political or social causes, could adversely affect our business, financial condition, or results of operations. Moreover, global climate change could result in certain types of natural disasters occurring more frequently or with more intense effects. The impacts of climate change may include physical risks (such as frequency and severity of extreme weather conditions), social and human effects (such as population dislocations or harm to health and well- being), compliance costs, transition risks, shifts in market trends, and other adverse effects. Such impacts may disrupt parties in our supply chain, our customers, and our operations. For example, the March 2011 earthquake and tsunami in Japan, and their aftermath, created economic uncertainty and disrupted economic activities in Japan, including a reduction in hospital spending. **More recently in September and October 2024, Hurricane Helene and Hurricane Milton caused economic uncertainty and business disruptions in the Southeast region of the U. S.** Physical risks associated with climate change are subject to increasing societal, regulatory, and political focus in the U. S. **, the EU,** and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity, or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures, or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities, and other customers, reduced workforce availability, increased costs or reduced supply of raw materials and components, increased liabilities, and decreased revenues than what we have experienced in the past from such events. The geographic location of our California headquarters and many of our manufacturing facilities, as well as the facilities of certain of our key suppliers and service providers, subject them to earthquake, drought, and wildfire risks. If a major earthquake, wildfire, or other natural disaster were to damage our facilities or the facilities of our suppliers and service providers, or impact the ability of our employees or the employees of our suppliers and service providers to travel to their workplace, we may experience potential impacts ranging from production and shipping delays to lost revenues and increased costs, which could harm our business. Moreover, periods with increased drought and annual periods of wildfire danger may increase the probability of planned power outages in the communities where we work and live. For example, in October 2019, Pacific Gas and Electric, the public electric utility in the Northern California region, used planned

power outages to avoid and contain wildfires sparked during strong wind events by downed power lines or equipment failure. If prolonged or frequent, such planned blackouts could impact our operations and the operations of our suppliers and service providers located in the Northern California region. While this danger has a low assessed risk of disrupting normal business operations, it has a potential impact on our employees' abilities to commute to work or to work from home and stay connected effectively. We do not have multiple- site capacity for all of our operations in the event of a business disruption, and we are predominantly self- insured and may not be able to sufficiently cover losses or additional expenses that we may sustain. Furthermore, the impacts of global climate change on water resources may result in water scarcity, which could impact our ability to access sufficient quantities of water in certain locations and result in increased costs. In addition, the increasing concern over climate change has resulted **,** and may continue to result **,** in more legal and regulatory requirements designed to mitigate the effects of climate change on the environment, including regulating greenhouse gas emissions, alternative energy policies, and sustainability initiatives. If such laws or regulations are more stringent than current legal or regulatory requirements, we may experience increased compliance burdens and costs to meet our regulatory obligations. **For example, under the EU' s Corporate Sustainability Reporting Directive (" CSRD "), we will be required to make certain disclosures in 2026 relating to our ESG impacts, risks, and opportunities for 2025, which may require that we change the processes by which we currently collect ESG- related data about our business. Furthermore, as ESG- related laws continue to evolve in scope and complexity, we may need to change the processes by which we currently operate our business and manage our supply chain to comply with these evolving legal and regulatory requirements, which, in turn, may have a material adverse effect on our business, financial condition, or results of operations. For instance,** ~~Changes~~ **changes** in requirements may adversely affect raw material sourcing from suppliers, our manufacturing operations and those of our suppliers, and the distribution of our products. Further, there may be increasing scrutiny and changing expectations from the market and other stakeholders with respect to ~~Environmental, Social, and Governance (~~ ESG ~~)~~ practices. Any such regulatory changes or increased market expectations could also have a significant effect on our operating and financial decisions, including those involving capital expenditures to reduce emissions and comply with other regulatory requirements or stakeholder expectations. ~~CONTINUED~~ **If we fail to comply with certain ESG- related laws, our products become non- compliant with such laws, or we fail to meet the expectations of our stakeholders on ESG- related matters, it could result in a loss of market access or a decline in our success in competitive bidding or public tender processes, and we could incur costs or face other sanctions, such as restrictions on our products entering certain jurisdictions, fines, and / or civil or criminal sanctions.** CONSOLIDATION IN THE HEALTHCARE INDUSTRY COULD HAVE AN ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. The healthcare industry has been consolidating, and organizations continue to consolidate purchasing decisions for many of our healthcare provider customers. Numerous initiatives and reforms by legislators, regulators, and third- party payers to curb the rising cost of healthcare have catalyzed a consolidation of aggregate purchasing power within the markets in which we sell our products. As the healthcare industry consolidates, competition to provide products and services is expected to continue to intensify, resulting in pricing pressures and decreased average selling prices. In addition, for smaller hospitals or groups that do not consolidate with larger networks, these entities may face increasing cost and / or competitive pressures, which could impact their ability to purchase additional products and services from us or make contractual payments over time. We expect that market demand, government regulation, third- party payor coverage and reimbursement policies, government contracting requirements, new entrants, technology, and societal pressures will continue to change the worldwide healthcare industry, resulting in further consolidation, which may exert further downward pressure on prices of our products and services and may have a material adverse impact on our business, financial condition, or results of operations. WE USE ESTIMATES, MAKE JUDGMENTS, AND APPLY CERTAIN METHODS IN DETERMINING OUR FINANCIAL RESULTS AND IN MEASURING THE PROGRESS OF OUR BUSINESS. AS THESE ESTIMATES, JUDGMENTS, AND METHODS CHANGE, OUR RESULTS OF OPERATIONS AND OUR ASSESSMENT OF THE PROGRESS OF OUR BUSINESS COULD VARY. The methods, estimates, and judgments we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates, and judgments are, by their nature, subject to substantial risks, uncertainties, and assumptions, and factors may arise over time that may lead us to change our methods, estimates, and judgments. Changes in any of our assumptions may adversely affect our reported financial results. We utilize methods for determining surgical market sizes, the number and type (cancerous or benign) of certain procedures performed, and the installed base of our systems that involve estimates and judgments, which are, by their nature, subject to substantial risks, uncertainties, and assumptions. Our estimates of surgical market sizes, the number and type of procedures performed, or the installed base of our systems do not have an impact on our results of operations but are used to estimate the progress of our business. Estimates and judgments for determining surgical market sizes, the number and type of procedures, and the installed base of our systems and the accuracy of these estimates may be impacted over time with changes in treatment modalities, hospital reporting behavior, system internet connectivity, distributor reporting behavior, increases in procedures per field employee, and other factors. In addition, from time to time, we may change the method for determining market sizes, the number and type of procedures, and the installed base of our systems, causing variation in our reporting. RISKS RELATING TO OUR REGULATORY ENVIRONMENT COMPLYING WITH FDA AND FOREIGN REGULATIONS IS A COMPLEX PROCESS, AND OUR FAILURE TO FULLY COMPLY COULD SUBJECT US TO SIGNIFICANT ENFORCEMENT ACTIONS. Because our products are commercially distributed, numerous quality and post- market regulatory requirements apply, including the following: • continued compliance with the FDA' s QSR, which requires manufacturers to follow design, testing, control, documentation, and other quality assurance procedures during the development and manufacturing process; • labeling regulations ~~; •~~ **, including** the FDA' s general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or " off- label " uses; • stringent complaint reporting and Medical Device Reporting regulations, which require that manufacturers keep detailed records of investigations or complaints against their devices and

report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; • adequate use of the corrective and preventive actions process to identify and correct or prevent significant, systemic failures of products or processes or in trends that suggest the same; and • the reporting of corrections **, recalls,** and removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FFDCA that may pose a risk to health. We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from inspectional observations (as set forth on FDA Form **-** 483) to a public Warning Letter to more severe civil and criminal sanctions, including the seizure of our products and equipment or ban on the import or export of our products. The FDA has, in the past, issued and could, in the future, issue Warning Letters or other adverse communications to us. If we fail to satisfy or remediate the matters discussed in any such Warning Letters or communications, the FDA could take further enforcement actions, including prohibiting the sale or marketing of the affected product. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition or results of operations. The receipt of a Warning Letter could place certain limits on the ability to obtain FDA- issued Certificates to Foreign Government (" CFGs ") used for new and re- registration of products in certain other countries. The FDA also strictly regulates labeling, advertising, promotion, and other activities relating to the marketing of our products. Medical devices may be promoted only for their cleared or approved indications and in accordance with the provisions of the cleared or approved label. It is possible that federal or state enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under a variety of statutory authorities, including under the FFDCA, as well as laws prohibiting false claims for reimbursement. In addition, any modification or change of medical devices cleared for the market requires the manufacturer to make a determination whether the change is significant enough to require new 510 (k) clearance. We have created labeling, advertising, and user training for the da Vinci surgical ~~system~~ **systems** to describe specific surgical procedures that we believe are fully within the scope of our existing 510 (k) indications for use stated in our 510 (k) clearances. Although we have relied on expert in- house and external staff, consultants, and advisors ~~, some of whom were formerly employed by the FDA and are familiar with the FDA perspective,~~ we cannot provide assurance that the FDA would agree that all such specific procedures are within the scope of the existing general clearance **. If the FDA or any comparable regulatory authority determines that** ~~or~~ **our promotion of our products for any such procedures represents promotion of an off- label use, the FDA or such regulator could request** that we ~~have compiled adequate information~~ **modify our labeling or promotional materials, or otherwise subject us** to ~~support~~ **regulatory or enforcement actions, including warning letters, untitled letters, injunctions, seizures, civil fines, or criminal penalties. In addition, from time to time, we modify our products, including** the ~~safety~~ **hardware** and **software in** ~~efficacy of using~~ the da Vinci surgical ~~system~~ **systems** ~~for all such specific procedures. From time to time, we modify our products, including the hardware and software in the da Vinci surgical system~~ , after we obtain 510 (k) clearance from the FDA for the devices in ways that we do not believe require new 510 (k) clearance. We cannot provide assurance that the FDA would agree in all cases with our determinations not to seek new 510 (k) clearance for any of these changes. If the FDA disagrees with our assessments that a new 510 (k) clearance was not required prior to commercializing the devices with these changes or modifications, then the FDA could impose enforcement sanctions **, require the recall of any modified products,** and / or require us to obtain 510 (k) clearance or other FDA marketing authorization ~~for~~ **before permitting the commercialization of** any **modified** ~~modification to our~~ products ~~. We~~ **, and we** may be **unable to obtain any** ~~prohibited from marketing the modified device until~~ such marketing ~~authorization~~ **authorizations** ~~is granted~~ **in a timely manner or at all** . We have a wholly owned manufacturing facility located in Mexicali, Mexico, which manufactures reusable and disposable surgical instruments. This facility is registered with the FDA as well as with Mexican authorities. The facility is operated under U. S. and international quality system regulations, including those applicable to Canada, the EU, **Brazil,** and Japan, among others. **This** ~~Our wholly owned manufacturing~~ facility ~~in Mexicali, Mexico~~ has an FDA Establishment Registration but has not been inspected by the FDA to date. If the FDA were to identify non- conformances in our product documentation or quality system compliance, it could hold indefinitely the importation of instruments at the border, which would deprive us of the ability to sell and supply the majority of our customers until the FDA requirements have been satisfied. Similar supply disruptions could occur if key suppliers outside of the U. S. were to encounter non- conformances with their documentation or quality system compliance. OUR PRODUCTS ARE SUBJECT TO A LENGTHY AND UNCERTAIN DOMESTIC REGULATORY REVIEW PROCESS. IF WE DO NOT OBTAIN AND MAINTAIN THE NECESSARY DOMESTIC REGULATORY AUTHORIZATIONS, WE WILL NOT BE ABLE TO SELL OUR PRODUCTS IN THE U. S. Our products and operations are subject to extensive regulation in the U. S. by the FDA. The FDA regulates the development and clinical testing, manufacturing, labeling, storage, record keeping, promotion, sales, distribution, and post- market support and medical device reporting in the U. S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In order for us to market products for use in the U. S., we generally must first obtain clearance from the FDA pursuant to Section 510 (k) of the FFDCA or approval of the product through the ~~premarket approval (" PMA ")~~ pathway. Clearance under Section 510 (k) requires demonstration that a new device is substantially equivalent to another device with 510 (k) clearance or grandfathered (" pre- amendment ") status and for which a PMA is not required. If we develop products in the future that are not considered to be substantially equivalent to a device with 510 (k) clearance or grandfathered status, we may be required to obtain marketing authorization through the more burdensome PMA process or alternatively through the de novo classification process, which is a path to market for novel devices that are low to moderate risk and for which a predicate device is not available. **Although our current products have generally been cleared through the 510 (k) clearance process, we may decide to seek approval for future products through a PMA submission or through the de novo classification process.** A PMA is typically a much more complex, lengthy, and burdensome application than a 510 (k)

and generally takes from one to three years, or **even longer, from the time the application is submitted to the FDA. In the PMA process, the FDA must determine that** a **proposed** ~~de novo classification request. To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the~~ device is safe and effective for its intended ~~uses~~ **use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical study, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting, or implantable devices. In the de novo classification process, a manufacturer whose novel device under the FFDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down- classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. Similarly, although the FDA has a statutory deadline of 120 days to review a de novo submission, in practice, the review may take much longer. In addition, a PMA application or de novo classification requests generally requesre the performance of one or more clinical studies** . In some cases, such studies may also be required to support a 510 (k) application **, and any requirements to conduct clinical studies beyond those we anticipate** ~~or~~ **for our current or future products could add significantly to our costs and have** a ~~de novo classification request~~ **material adverse effect on our business** . The FDA may not act favorably or quickly in its review of any marketing application submissions, or we may encounter significant difficulties and costs in our efforts to obtain marketing authorization from the FDA, either of which could delay or preclude the sale of new products in the U. S. In addition, the FDA may place significant limitations upon the intended use of our products as a condition of granting marketing authorization. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following marketing authorization. Any delays or failure to obtain FDA marketing authorization for new or modified products that we develop, any limitations imposed by the FDA on new product use, or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition, or results of operations. In addition, the FDA or other regulatory agencies may change their policies, adopt additional regulations, revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. We may be found non- compliant as a result of future changes in, or interpretations of, regulations by the FDA or other regulatory agencies. For example, ~~on~~ **in** February ~~23, 2022~~ **2024** , the FDA issued a ~~proposed~~ **final** rule to amend **and replace** the QSR, which ~~establishes~~ **sets forth the FDA' s** current good manufacturing practice requirements for medical ~~device~~ **devices** ~~manufacturers~~ , to align more closely with the International Organization for Standardization (" ISO ") standards. **Specifically,** ~~This~~ **this** ~~proposal~~ **final rule, which the FDA expects to go into effect on February 2, 2026, establishes the " Quality Management System Regulation " (" QMSR "), which among other things, incorporates by reference the quality management system requirements of ISO 13485: 2016. Although the FDA** has ~~not yet been finalized or adopted. Accordingly~~ **stated that the standards contained in ISO 13485: 216 are substantially similar to those set forth in the QSR** , it is unclear the extent to which this **final rule** ~~or any other proposals~~ , ~~if adopted~~ **once effective** , could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise ~~create competition that may~~ negatively affect our business **. If we are unable to comply with QMSR, once effective, or with any other changes in the laws or regulations enforced by FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition, or results of operations** . Additionally, in September 2019, the FDA issued revised guidance describing an optional " safety and performance based " premarket review pathway for manufacturers of " certain, well- understood device types " to demonstrate substantial equivalence under the 510 (k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list of device types appropriate for the " safety and performance based " pathway and continues to develop product- specific guidance documents that identify the performance criteria for each such device type, as well as the recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510 (k) clearances or otherwise create competition that may negatively affect our business. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain IRB approval of the proposed investigation. In addition, if the clinical study involves a " significant risk " (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an IDE application. Many of our products to date have been or would be considered significant risk devices requiring IDE approval prior to investigational use. We may not be able to obtain FDA and / or IRB approval to undertake clinical trials in the U. S. for any new devices that we intend to market in the U. S. in the future. Even if we obtain such approvals, we may not be able to conduct studies that comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes and, if we fail to complete our planned or ongoing clinical trials or if such clinical trials produce negative or inconclusive results, we may be delayed or prevented from obtaining regulatory clearances or approvals to commercialize our products for new or expanded indications. Additionally, we may experience delays in our ongoing clinical trials for any number of reasons, which could adversely affect the costs, timing, or successful completion of our clinical trials. If we fail to complete our planned and ongoing clinical trials or if such clinical trials produce negative or inconclusive results, we may be delayed or prevented from obtaining regulatory clearances or approvals to commercialize our products for new or expanded indications, which may limit the market for our products. **Certainty that clinical trials will meet desired endpoints, produce meaningful or useful data, and be free of unexpected adverse effects or that the FDA will accept the validity of foreign clinical study**

data cannot be assured, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition, or results of operations ~~. Certainty that clinical trials will meet desired endpoints, produce meaningful or useful data, and be free of unexpected adverse effects or that the FDA will accept the validity of foreign clinical study data cannot be assured, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue~~ . OUR PRODUCTS MAY CAUSE OR CONTRIBUTE TO ADVERSE MEDICAL EVENTS OR BE SUBJECT TO FAILURES OR MALFUNCTIONS THAT WE ARE REQUIRED TO REPORT TO THE FDA AND FOREIGN REGULATORY AUTHORITIES AND, IF WE FAIL TO DO SO, WE WOULD BE SUBJECT TO SANCTIONS THAT COULD HARM OUR REPUTATION, BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. We are subject to the FDA' s medical device reporting regulations and similar foreign regulations, which require us to report to the FDA and foreign regulatory authorities when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed time frame. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or foreign regulatory authorities could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, approval, or certification, seizure of our products or delay in clearance, approval, or certification of future products. The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in the design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government - mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new clearances, approvals, or certifications for the device before we may market or distribute the corrected device. Seeking such clearances, approvals, or certifications may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement actions, including FDA or foreign regulatory authorities warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory authorities. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory authorities. If the FDA or foreign regulatory authorities disagree with our determinations, it could require us to report those actions as recalls, and we may be subject to enforcement actions. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us, and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business, and may harm our reputation ~~and~~ **,** financial **condition, or** results **of operations** . IF OUR MANUFACTURING FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE, OR OTHER MANUFACTURING **REGULATIONS AND** STANDARDS, WE MAY BE REQUIRED TO TEMPORARILY CEASE ALL OR PART OF OUR MANUFACTURING OPERATIONS, IMPORT / EXPORT OF OUR PRODUCTS, AND / OR RECALL SOME PRODUCTS, WHICH ~~WOULD~~ **COULD** RESULT IN SIGNIFICANT PRODUCT DELIVERY DELAYS AND LOST REVENUE. Our manufacturing facilities are subject to periodic inspection by regulatory authorities and **audit by** notified bodies, and our operations will continue to be regulated and inspected by the FDA and other regulatory agencies and notified bodies for compliance with Good Manufacturing Practice requirements contained in the QSR and other regulatory requirements. We are also required to comply with ISO quality system standards as well as EU legislation and norms in order to produce products for sale in the EU. In addition, many countries, such as Canada and Japan, have very specific additional regulatory requirements for quality assurance and manufacturing. If we fail to continue to comply with Good Manufacturing Practice requirements, as well as ISO or other regulatory standards, we may be required to cease all or part of our operations until we comply with these regulations. We continue to be subject to FDA and certain other inspections by other regulatory authorities and notified bodies at any time. Maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with Good Manufacturing Practice requirements or ISO standards and other regulatory requirements in future inspections and audits by regulatory authorities and notified bodies. We are currently participating in the Medical Device Single Audit Program (" MDSAP "), which allows an MDSAP- recognized auditing organization to conduct a single regulatory audit of a medical device manufacturer that evaluates our quality system to assess compliance with the requirements of multiple regulatory jurisdictions, including the U. S., Japan, Brazil, Australia, and Canada. The information collected in an MDSAP audit is shared and reviewed amongst all the regulatory authorities participating in the MDSAP, who may or may not determine that additional information or auditing is required. Our Sunnyvale, California facility is licensed by the State of California to manufacture medical devices. We have been subject to periodic inspections by the California Department of Health Services Food and Drug Branch and, if we are unable to maintain this license following any future inspections, we will be unable to manufacture or ship some products, which would have a material adverse effect on our results of operations. In addition, both

our Sunnyvale, California and Mexicali, Mexico facilities are subject to periodic inspections by other regulatory bodies, including third- party auditors on behalf of national regulatory authorities. Compliance with multiple regulatory standards is complex, difficult, and costly to maintain, and material deficiencies could result in significant limitations on our ability to manufacture, transport, and sell our products in one or more countries. OUR PRODUCTS ARE SUBJECT TO INTERNATIONAL REGULATORY PROCESSES AND APPROVAL OR CERTIFICATION REQUIREMENTS. IF WE DO NOT OBTAIN AND MAINTAIN THE NECESSARY ~~INTERNATIONAL~~ REGULATORY **REQUIREMENTS** ~~APPROVALS OR CERTIFICATIONS~~ , WE WILL NOT BE ABLE TO SELL OUR PRODUCTS IN OTHER COUNTRIES. To be able to sell our products in other countries, we must obtain regulatory approvals or certifications and comply with the regulations of those countries, which may differ substantially from those of the U. S. These regulations, including the requirements for approvals or certifications and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals or certifications is complex, and the time to obtain clearances or certifications in other countries varies; therefore, we cannot be certain that we will receive regulatory approvals or certifications in any other country in which we plan to market our products or obtain such approvals or certifications on a favorable schedule. If we fail to obtain or maintain regulatory approval or certification in any other country in which we plan to market our products, our ability to generate revenue will be harmed. In particular, if the FDA refuses to provide CFGs, our ability to register products or renew such registrations may be delayed or denied. For instance, one of the most significant **changes in** ~~moving targets related to~~ the regulatory landscape is in the EU; more specifically, the regulation of medical devices has ~~recently~~ evolved **and may be subject to further developments in 2025** . The EU Medical Devices Regulation, which ~~repeals~~ **repealed** and ~~replaces~~ **replaced** the EU Medical Devices Directive, became applicable on May 26, 2021. In accordance with ~~its recently extended~~ transitional provisions, both (i) devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021, and (ii) legacy devices lawfully placed on the EU market from May 26, 2021, in accordance with the EU Medical Devices Regulation transitional provisions may generally continue to be made available on the market or put into service until December 31, 2028 (at the very latest and depending on the product risk classification) per the EU Medical Devices Regulation extended transitional provisions, provided that the requirements of the transitional provisions are fulfilled. However, since May 26, 2021, manufacturers must already comply with a number of new, or reinforced, requirements set forth in the EU Medical Devices Regulation, including registration of economic operators and of devices control plan, Periodic Safety Update Report (“ PSUR ”), notify body periodic vigilance report, post- market surveillance, clinical periodic review report, and vigilance requirements **, such as the Post Market Clinical Follow- Up (“ PMCF ”) or Clinical Evaluation Plan (“ CEP ”)** . Subject to the transitional provisions, in order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation. Compliance with these requirements is a prerequisite to be able to affix the 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 Annex I to the EU Medical Devices Regulation, including the requirement 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. It is the responsibility of the (manufacturer) Person Responsible for Regulatory Compliance (“ PRRC ”) to ensure such requirements are fulfilled and in place in the company. 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 that 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 and may include a technical documentation assessment and an onsite audit. Except for low- risk medical devices (Class I), where the manufacturer can self- assess the conformity of its products with the general safety and performance requirements (except for any parts that relate to sterility, metrology, or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design, and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements and we have the organizational structure to support it (i. e., PRRC), the notified body issues a certificate of conformity, 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 comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU or any countries recognizing the CE mark. The aforementioned EU rules are generally applicable in the EEA. **We have gained** ~~In January 1999, further to their~~ certification **under** ~~by our notified body, Presafe, we affixed~~ the **EU Medical Devices Regulation** ~~CE mark to our da Vinci surgical system~~ and ~~EndoWrist instruments~~ , ~~attesting compliance with~~ **where appropriate, maintained our certificates granted under** the former EU Medical Devices Directive ~~, and we have maintained these certifications continuously since that time. Subsequent products and accessories have also received certifications by our notified body in accordance with the former EU Medical Devices Directive. Where required, we are maintaining our certificates granted under the former EU Medical Devices Directive and have either gained, or are working towards, certification under the EU Medical Devices Regulation~~ for all medical devices that we intend to continue to market in the EU and EEA ~~. Should we not gain such certification, this would prevent us from selling our products in the EU and EEA. Should we not gain such certification by the end of the transitional period currently set forth in the EU Medical Devices Regulation of December 31, 2027, for higher classification devices (Class III and certain Class IIb implantable devices), and December 31, 2028 for medium- and lower- risk devices (for the other Class IIb devices, Class IIa devices, and some Class I devices), it would prevent us from selling our products in the EU and EEA. We are committed to complying with the EU Medical Devices Regulation for our legacy devices as well as any new device introduction in the market for the first time,~~

~~transitioning progressively toward the EU Medical Devices Regulation and, in parallel, benefiting from the EU Medical Devices Regulation transitional provisions to continue marketing our devices in the EU and the EEA under their EU Medical Devices Directive certification until we obtain our new certifications~~ . Further, Switzerland, which is the country from which we import our products into the EU and where our EU regulatory team is based, has not yet entered into a Mutual Recognition Agreement with the EU that covers the EU Medical Device Regulation and allows medical devices to move freely between Switzerland and the EU. Therefore, for future needs, we will adjust the manner in which we bring our products into the EU market. Any such adjustments could cause temporary disruptions in and have adverse financial implications to our business in Europe. ~~To~~ **In Japan, to** date, we received approvals from the Japanese Ministry of Health, Labor and Welfare for our da Vinci Si, Xi, X, and SP surgical systems and various associated instruments and accessories for use in certain da Vinci procedures. We may seek additional approvals for other products and / or indications; however, there can be no assurance that such approvals will be granted. In addition, because not all of our instruments have received product approvals and reimbursement is an additional process to generate market acceptance, it is possible that procedures will be adopted slowly or not at all. Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities. There are multiple pathways to obtain reimbursement for procedures including those that require in- country clinical data and which are considered for reimbursed status in April of even- numbered years. If we are not successful in obtaining the necessary reimbursement approvals or obtaining approvals for future products and procedures, then the demand for our products could be limited. These limitations could eliminate a significant market opportunity for our products in Japan. ~~Our~~ **In China, our** capital sales ~~in China~~ are subject to importation authorizations and purchasing tender processes. In June 2023, the China National Health Commission published the **2023** ~~14th five- year plan quota~~ **Quota** ~~for major medical equipment to be sold in China on its official website~~ . Under the 2023 Quota, the government will allow for the sale of 559 new surgical robots into China, which could include da Vinci surgical systems as well as surgical systems introduced by others. **As of December 31, 2024, including systems that were sold in prior quarters, we have placed 121 da Vinci surgical systems under the 2023 Quota. Our ability to track the number of systems that could be sold under these quotas in the future is limited by provincial and national agencies making such information publicly available.** Future system sales and our ability to grow future procedure volumes are dependent on the completion of these purchasing tender authorizations. The timing and magnitude of these future authorizations, which may determine our system placements in future years, is not certain, and we expect to continue to experience variability in the timing of capital sales in China. CHANGES IN HEALTHCARE LEGISLATION AND POLICY MAY HAVE **AN** ~~A MATERIAL~~ ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. In the U. S., there have been, and continue to be, a number of legislative initiatives to contain healthcare costs. In March 2010, the ACA was enacted, which made changes that have impacted and are expected to significantly impact the pharmaceutical and medical device industries. The ACA contained a number of provisions designed to generate the revenues necessary to fund health insurance coverage expansions among other things. This included a number of Medicare 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 healthcare services through bundled payment models and appropriated funding for comparative effectiveness research. Since its enactment, there have been judicial, executive branch, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. In addition, other legislative changes have been proposed and adopted since the ACA became law. These changes included an aggregate reduction in Medicare payments, which went into effect on April 1, 2013, and will remain in effect through 2032, unless additional Congressional action is taken, with the exception of a temporary suspension due to the COVID- 19 pandemic from May 1, 2020, through March 31, 2022 ~~. On January 2, 2013, the American Taxpayer Relief Act of 2012 became law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers, and cancer treatment centers. MACRA repealed 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 that began in 2019 and are based on various performance measures and physicians' participation in alternative payment models, such as accountable care organizations~~ . Individual states in the U. S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints and discounts, and require marketing cost disclosure and transparency measures. We expect additional state and federal healthcare reform measures to be adopted in the future that could have a material adverse effect on our industry generally and on our customers. Any changes to, or uncertainty with respect to, future reimbursement rates or changes in hospital admission rates could impact our customers' demand for our products and services, which, in turn, could have a material adverse effect on our business, financial condition, or results of operations. Further, the federal, state, and local governments, Medicare, Medicaid, managed- care organizations, and foreign governments have, in the past, considered, are currently considering, and may, in the future, consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. Future significant changes in the healthcare systems in the U. S. or other countries, including retroactive and prospective rate and coverage criteria changes, competitive bidding or tender processes for certain products and services, and other changes intended to reduce expenditures along with uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether other healthcare policies, including policies stemming from legislation or regulations affecting our business may be proposed or enacted in the future, what effect such policies would have on our business, or what effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers. For instance, in December 2021, the EU Regulation No. 2021 / 2282 on Health Technology Assessment, 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~~ **2028** onwards, with preparatory and implementation- related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. This Regulation intends to boost cooperation among EU member states in assessing health technologies, including certain high- risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It 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 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, etc.) aspects of health technology and making decisions on pricing and reimbursement. WE ARE SUBJECT TO FEDERAL, STATE, AND FOREIGN LAWS GOVERNING OUR BUSINESS PRACTICES, WHICH, IF VIOLATED, COULD RESULT IN SUBSTANTIAL PENALTIES. ADDITIONALLY, CHALLENGES TO, OR INVESTIGATION INTO, OUR PRACTICES COULD CAUSE ADVERSE PUBLICITY AND BE COSTLY TO RESPOND TO AND, THUS, COULD HARM OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. The Dodd- Frank Wall Street Reform and Consumer Protection Act requires us to track and disclose the source of any tantalum, tin, gold, and tungsten used in manufacturing that may originate in the Democratic Republic of the Congo or adjoining regions (so called " conflict minerals "). These metals are central to the technology industry and are present in some of our products as component parts. In most cases, no acceptable alternative material exists that has the necessary properties that our products require. Because it is not possible to determine the source of the metals by analysis, we must obtain a good faith description of the source of the intermediate components and raw materials from parties in our supply chain. The components that incorporate those metals may originate from many sources, and we purchase fabricated products from manufacturers who may have a long and difficult- to- trace supply chain. As the spot price of these materials varies, producers of the metal intermediates can be expected to change the mix of sources used. Accordingly, components and assemblies we buy may have a mix of sources as their origin. We are required to carry out a diligent effort to determine and disclose the source of these materials. There can be no assurance that we can obtain this information accurately or reliably, or at all, from intermediate producers who may be unwilling or unable to provide this information or further identify their sources of supply or to notify us if these sources change. In addition, these metals are subject to price fluctuations and shortages that can affect our ability to obtain the manufactured materials that we rely on at favorable terms or from consistent sources. These changes could have an adverse impact on our ability to manufacture and market our devices and products. We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we conduct our business. The healthcare laws and regulations that may affect our ability to operate include the federal Anti- Kickback Statute, which prohibits the payment of remuneration to induce or reward hospitals, physicians, or other healthcare professionals either to refer patients or to purchase, lease, order, or arrange for or recommend the purchase, lease, or order of healthcare products or services for which payment may be made under the federal healthcare programs, such as Medicare, Medicaid, and other third- party payor programs. Further, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Similar laws must be complied with at the state level and in foreign jurisdictions. We must comply with the federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent. Although we do not submit claims directly to government payors, manufacturers can be held liable under the federal False Claims Act if they are deemed to " cause " the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off- label. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The Health Insurance Portability and Accountability Act of 1996, which created additional federal criminal statutes prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. 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 to have committed a violation. These laws may affect our sales, marketing, and other promotional activities by limiting the kinds of financial arrangements that we may have with hospitals, physicians, or other potential purchasers of our products. They particularly impact how we structure our sales offerings, including discount practices, customer support, speaker, education, and training programs, physician consulting, and other service arrangements. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. Violating anti- kickback laws and false claims laws can result in civil and criminal fines and penalties, which can be substantial and include monetary damages and penalties, imprisonment, and exclusion from government healthcare programs. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to defend and, thus, could harm our business, financial condition, or results of operations. The federal Physicians Payments Sunshine Act imposes reporting and disclosure requirements on certain device manufacturers for any " transfer of value " made or distributed to physicians (including family members), as defined by statute, certain non- physician practitioners, including physician assistants and nurse practitioners, and teaching hospitals. Such information must be made publicly available in a searchable format. In addition, device manufacturers are required to report and disclose any ownership or investment interests held by physicians and their immediate family members, as well as any transfers of value made to such physician owners and investors, during the preceding calendar year. Similar requirements apply in foreign jurisdictions. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value, or ownership or investment interests not reported in an annual submission. Device manufacturers are required to submit reports to CMS by the 90th day of each calendar year. Many states have similar laws and

regulations, such as anti- kickback and false claims laws, which may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws, impose restrictions on device manufacturer marketing practices, and / or require the tracking and reporting of gifts, compensation, and other remuneration to physicians or marketing expenditures and pricing information. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may be found out of compliance with one or more of the requirements, subjecting us to significant civil monetary penalties. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws. Compliance with complex foreign and U. S. laws and regulations that apply to our OUS operations increases our cost of doing business in foreign jurisdictions and could expose us or our employees to fines and penalties in the U. S. and / or abroad. These numerous, and sometimes conflicting, laws and regulations include U. S. laws, such as the FCPA, and similar laws in other countries, such as the **UK** ~~U. K.~~ Bribery Act ~~of 2010~~ . Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business, and damage to our reputation. Although we have implemented policies and procedures designed to ensure compliance with these laws, there can be no assurance that our employees, contractors, or agents will not violate our policies. Our operations are subject to certain antitrust and competition laws in the jurisdictions in which we conduct our business, in particular the U. S. and the EU. These laws prohibit, among other things, anticompetitive agreements and practices. If any of our commercial agreements or practices are found to violate or infringe such laws, we may be subject to civil and other penalties. We may also be subject to third- party claims for damages. Further, agreements that infringe upon these antitrust and competition laws may be void and unenforceable, in whole or in part, or require modification in order to be lawful and enforceable. If we are unable to enforce our commercial agreements, whether at all or in material part, our business, financial condition, or results of operations could be adversely affected. We are also subject to claims, lawsuits, and government investigations involving labor and employment. Such claims, lawsuits, and government investigations are inherently uncertain. Regardless of the outcome, any of these types of legal proceedings can have an adverse impact on us because of legal costs, diversion of management resources, and other factors. We are also exposed to the risk that our employees, independent contractors, consultants, manufacturers, suppliers, and any other third parties that we may engage in connection with the development and commercialization of our products may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless, and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar regulatory authorities, including those laws requiring the reporting of true, complete, and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud, and abuse laws and regulations; or (iv) laws that require the true, complete, and accurate reporting of financial information or data. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or the creation of fraudulent data in clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business or results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U. S. federal healthcare programs, or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. IF HOSPITALS AND OTHER ~~SURGERY~~ **SURGICAL** FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE, OR OTHER REGULATORY STANDARDS, THEY MAY BE REQUIRED TO TEMPORARILY CEASE ALL OR PART OF THEIR SYSTEM UTILIZATION. Our global customers are subject to periodic inspection by regulatory authorities. Our customers are required to comply with applicable ~~local and international~~ regulations, including with respect to the reprocessing of our instruments and accessories. Hospitals may not follow cleaning and sterilization instructions properly, or equipment used for cleaning and sterilization may malfunction or be used improperly. If our customers deviate from cleaning and sterilization instructions, regulatory authorities may require them to suspend the use of our systems. RISKS RELATING TO OUR INTELLECTUAL PROPERTY IF WE ARE UNABLE TO FULLY PROTECT AND SUCCESSFULLY DEFEND OUR INTELLECTUAL PROPERTY FROM USE BY THIRD PARTIES, OUR ABILITY TO COMPETE IN THE MARKET MAY BE HARMED. Our commercial success depends in part on obtaining patent protection for the proprietary technologies contained in our products and on successfully defending our patents against infringing products and / or services in litigation or administrative proceedings, including patent oppositions, reviews, or reexaminations. We incur substantial costs in obtaining patents and, if necessary, defending our patent rights. We do not know whether we will be successful in obtaining the desired patent protection for our new proprietary technologies or that the protection we do obtain will be found valid and enforceable when challenged. The success of defending our proprietary rights can be highly uncertain, because it involves complex and often evolving legal issues and procedures that are dependent on the particular facts of each case. In addition to patents, we also rely on other intellectual property rights, such as trade secret, copyright, and trademark laws to protect proprietary technologies. We further utilize nondisclosure agreements and other contractual provisions as well as technical measures to protect our proprietary technologies. Nevertheless, these measures may be inadequate in protecting our technologies. If these measures prove to be inadequate in protecting our technologies, our competitive advantages may be reduced. Moreover, we may not have adequate

remedies for potential breaches by employees, consultants, and others who participate in developing our proprietary technologies against their agreements with us regarding intellectual property. As a result, our trade secrets may be lost. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal to or superior to our technologies without infringing any of our intellectual property, which would harm our ability to compete in the market. As foreign markets become more significant in revenue for us, our foreign operations and strategic alliances with foreign entities will likely increase. Our exposure to risks associated with these operations requires us to increase our reliance on protecting our intellectual property against infringing products and / or services in markets outside of the U. S. The laws and judicial systems in these countries may introduce yet another level of uncertainty in our effort to obtain the desired protection as well as defending our rights. OTHERS MAY BE SUCCESSFUL IN ASSERTING THAT OUR PRODUCTS INFRINGE THEIR INTELLECTUAL PROPERTY RIGHTS, WHICH MAY CAUSE US TO PAY SUBSTANTIAL DAMAGES AND / OR ENJOIN US FROM COMMERCIALIZING OUR PRODUCTS. As we continue to introduce and commercialize new products and technologies, there may be U. S. and foreign patents issued to third parties that relate to our products. Some of these patents may be broad enough to cover one or more aspects of our products. We do not know whether any of these patents, if challenged, would be held valid, enforceable, and infringed. From time to time, we receive, and likely will continue to receive, letters from third parties accusing us of infringing and / or inviting us to license their patents. We may be sued by, or become involved in an administrative proceeding with, one or more of these third parties. We cannot be certain that a court or administrative body would agree with any arguments or defenses that we may have concerning invalidity, unenforceability, or non- infringement of any third- party patent. In addition, other parties may have filed or will file patent applications covering products that are similar to or identical to ours. We cannot be certain that patents issuing from our own patent applications covering our products will have a priority date over any patents issuing from applications filed by a third party. The medical device industry has experienced extensive intellectual property litigation and administrative proceedings. If third parties assert infringement claims or institute administrative proceedings against us, our technical and management personnel will need to spend significant time and effort, and we will incur large expenses in defending against these attacks. We cannot be certain that we will prevail in defending against infringement, validity, or enforceability claims against us. If plaintiffs in patent administrative proceedings are successful, our patent portfolio may be adversely affected. If plaintiffs in any patent action are successful, we may be enjoined from selling or importing our products, we may have to pay substantial damages, including treble damages, or we may be required to obtain a license that requires us to pay substantial royalties or relocate our manufacturing facilities. In addition, any public announcements related to litigation or administrative proceedings initiated or threatened against us could cause our stock price to decline. OUR PRODUCTS **MAY** RELY ON LICENSES FROM THIRD PARTIES, WHICH MAY NOT BE AVAILABLE TO US ON COMMERCIALLY REASONABLE TERMS OR AT ALL. IF WE LOSE ACCESS TO THESE TECHNOLOGIES, OUR REVENUES COULD DECLINE. ~~We~~ **Our products may** rely on technology that we license from others, including technology that is integral to our products. There is no assurance that we can obtain or retain licenses on acceptable terms or at all. The license agreements we have entered into with several industry partners may be terminated for breach. If any of these agreements are terminated, we may be unable to reacquire the necessary license on satisfactory terms or at all. The failure to obtain, retain, or maintain licenses could prevent or delay further development or commercialization of our products, which may have a material adverse effect on our business, financial condition, or results of operations. GENERAL RISK FACTORS OUR FUTURE OPERATING RESULTS MAY BE BELOW ~~SECURITIES ANALYSTS' OR INVESTORS'~~ EXPECTATIONS, WHICH COULD CAUSE OUR STOCK PRICE TO DECLINE. Due to the nascent nature of our industry, we have limited insight into trends that may emerge in our market and affect our business. The revenue and income potential of our market are unproven, and we may be unable to maintain or grow our revenue **or income** . Our products typically have lengthy sales cycles. In addition, our costs may be higher than we anticipated. If we fail to generate sufficient revenues or our costs are higher than we expect, our results of operations may be materially adversely affected. Further, future revenue from sales of our products is difficult to forecast, because the market for new surgical technologies is still evolving. Our results of operations could be impacted by numerous factors, including: • the extent to which our products achieve and maintain market acceptance; • actions relating to regulatory matters; • product quality and supply problems; • inflationary pressures on the cost of producing and distributing our products; • our timing and ability to develop our manufacturing and sales and marketing capabilities; • demand for our products **; • the utilization of our systems placed under usage- based operating lease arrangements** ; • the size and timing of particular sales and any collection delays related to those sales; • the progress of surgical training in the use of our products; • our ability to develop, introduce, and market new or enhanced versions of our products on a timely basis; • third- party payor reimbursement policies; • our ability to protect our proprietary rights and defend against third- party challenges; • our ability to license additional intellectual property rights; and • the progress and results of any clinical trials. Our operating results in any particular period will not be a reliable indication of our future performance. It is possible that, in future periods, our operating results will be below the expectations of securities analysts or investors. If this occurs, the price of our common stock and the value of your investment will likely decline. OUR STOCK PRICE HAS BEEN, AND WILL LIKELY CONTINUE TO BE, VOLATILE. The market price of our common stock has experienced fluctuations and may fluctuate significantly in the future. For example, during ~~2021~~ **2022** , the adjusted closing price of our common stock reached a high of $ ~~365~~ **360** . ~~42~~ **00** and a low of $ ~~228~~ **183** . ~~30~~ **06** ; during ~~2022~~ **2023** , it reached a high of $ ~~360~~ **354** . ~~00~~ **93** and a low of $ ~~183~~ **224** . ~~06~~ **75** ; and, during ~~2023~~ **2024** , it reached a high of $ ~~354~~ **550** . ~~93~~ **62** and a low of $ ~~224~~ **322** . ~~75~~ **13** . Our stock price can fluctuate for a number of reasons, including: • announcements about us or our competitors; • variations in our operating results and financial guidance; • our introduction or abandonment of new technologies or products; • regulatory approvals and enforcement actions; • changes in our product pricing policies; • changes in earnings estimates or recommendations by analysts ~~; • changes in accounting policies~~ ; • economic changes and overall market volatility; • announcements relating to product quality and the supply chain for our products; • litigation; • media coverage, whether

accurate or inaccurate, fair or misleading; • political uncertainties; • short sales on shares of our common stock or other activities by short sellers; and • our stock repurchase program. Future stock repurchase programs will be contingent on a variety of factors, including our financial condition, results of operations, and business requirements. There can be no assurance that we will continue repurchasing our common stock in the future, consistent with historical levels or at all, or that our stock repurchase programs will have a beneficial impact on our stock price. In addition, stock markets generally have experienced, and in the future may experience, significant price and volume volatility. This volatility has a substantial effect on the market prices of securities of many public companies for reasons frequently unrelated or disproportionate to the operating performance of the specific companies. Further, the securities of many medical device companies, including us, have historically been subject to extensive price and volume fluctuations that may affect the market price of their common stock. If these broad market fluctuations continue, it may have a material adverse impact on the market price of our common stock. CHANGES TO FINANCIAL ACCOUNTING STANDARDS MAY AFFECT OUR REPORTED RESULTS OF OPERATIONS. A change in accounting standards can have a significant effect on our reported results and may retroactively affect previously reported results. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing standards or the reevaluation of current practices may adversely affect our reported financial results or the way we conduct our business.