Risk Factors Comparison 2024-01-31 to 2023-02-10 Form: 10-K

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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 and additional or unforeseen effects from ~~the~~ COVID- 19 ~~pandemic~~ amplify many of these risks. RISKS RELATING TO OUR BUSINESS MACROECONOMIC CONDITIONS COULD HAVE A MATERIALLY ADVERSE...... with many of these claims. BECAUSE 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~~ **surgical** ~~System~~ **system** or robotic- assisted bronchoscopy ~~using~~ **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 more effective or less expensive than using our products, which could render our products obsolete or unmarketable. Studies could be published that show that other treatment options are more beneficial and / or cost- effective than robotic- assisted medical procedures. **For example, in 2023, certain drugs initially approved for use in diabetes patients gained market acceptance for use in weight loss following FDA approvals for weight loss indications. The availability and effectiveness of weight loss drugs have adversely impacted our da Vinci surgical system bariatric procedures by causing some patients to reconsider the surgical option. At this time, it is difficult to predict the long- term market impact of these drugs, including their long- term efficacy 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 face or expect to face competition from companies that develop or have developed wristed, 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, but not limited to, the following companies: Asensus Surgical, Inc.; ~~avateramedical GmbH~~ **Beijing Surgerii Robotics Company Limited** ; CMR Surgical Ltd.; Johnson & Johnson; Medicaroid Corporation; ~~Medrobotics Corporation;~~ Medtronic plc; meerecompany Inc.; **Noah Medical** ~~Olympus Corporation; Samsung Electronics Co., Ltd~~ ; Shandong Weigao Group Medical Polymer Company Ltd.; Shanghai Microport Medbot (Group) Co., Ltd.; and ~~Titan~~ **Shenzhen Edge** Medical ~~Inc~~ **Co., Ltd** . Other companies with substantial experience in industrial robotics could potentially expand into the field of medical robotics and become competitors. 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 ~~provide services~~ - **service** ~~to~~ da Vinci ~~Surgical~~ **surgical** ~~System~~ **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. Macroeconomic conditions, such as high inflationary pressure, changes to monetary policy, high interest rates, volatile currency 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, concerns about the stability and liquidity of certain financial institutions, the introduction of 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 operations. Recent macroeconomic conditions have been adversely impacted by geopolitical instability and military hostilities in multiple geographies (including the conflict between Ukraine and Russia and the conflict between Israel and Hamas), 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 resulted in, and may continue to result in, higher inflation in the U. S. and globally, which is likely, in turn, to 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. 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, on March 10, 2023, Silicon Valley Bank (" SVB ") was closed by the California Department of Financial Protection and Innovation, which appointed the U. S. Federal Deposit Insurance Corporation (" FDIC ") as receiver. Similarly, other institutions have been, and may continue to be, swept into receivership. Uncertainty may remain over liquidity concerns in the broader financial services industry, 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 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 increased interest rates and restraints on credit. Hospitals and distributors may also be adversely affected by the liquidity concerns in the broader financial services industry, as described above, that could result in delayed access 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. Hospitals, in particular, are experiencing and may continue to experience financial and operational pressures as a result of staffing shortages, the supply chain environment, and high 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, defer elective surgeries, and impact their 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 could have a material adverse effect on our business, financial condition, or results of operations. Additionally, with economic uncertainty, an increase in unemployment rates, and increasing health insurance premiums, 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 or are not sustained long enough to bring inflation to lower, more acceptable levels, hospitals' ability or willingness to spend on capital equipment may be impacted for a prolonged period of time. If a recession occurs, economies weaken, or inflationary trends continue, our business and operating results could be materially adversely affected. Also, we have, 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 continue to rise, 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. Such supply chain constraints could cause us to fail to meet product demand, which 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 34 %, 33 %, and 33 % of our revenue for the years ended December 31, 2023, 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; • protectionist laws, policies, and business practices that favor local competitors or lead to non- U. S. customers favoring domestic technology solutions, which could slow our growth 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; • anti- corruption laws, such as the U. S. Foreign Corrupt Practices Act (" FCPA "), and other local laws prohibiting corrupt payments to government officials; • 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. 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. 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 these regulations do not materially adversely impact our business at this time but 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 July 2023, the Chinese government launched a one- year anti- corruption campaign targeting the healthcare sector. The efforts of this campaign largely aim to curb kickbacks and corruption among individuals who have exploited their positions within medical institutions. As a result of this anti- corruption campaign, 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 third and fourth quarters of 2023, the effect of this anti- corruption campaign contributed to fewer systems being placed in China. Currently, the extent of the impact of this anti- corruption campaign on our business remains uncertain. 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, 2022, the MHRA published its response to a 10- week consultation on the future regulation of medical devices in the UK. Regulations implementing the new regime were originally scheduled to come into force in July 2023 but the MHRA has confirmed that it is aiming for the core aspects of the new regime to apply from July 2025. Devices which have valid CE certification issued by EU notified bodies under 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. 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. 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, 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, 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. The individuals who have brought the product liability claims seek recovery for their alleged personal injuries and, in many cases, punitive damages. Current product liability claims have resulted in negative publicity regarding our Company, and these and any other product liability or negligence claims or product recalls 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 lawsuits and proceedings or otherwise be excluded under the terms of any insurance policy. 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. 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 could also be subject to governmental investigations in connection with many of these claims. 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 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. Difficulties remain in obtaining a sufficient supply of semiconductor and other component materials, and we expect such difficulties to persist in the foreseeable future. Prices of such materials have also increased, and global supply 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. 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, 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 success, and our research and development projects may not be successful. We may be unable to 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, and such 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 demand for our current products, thereby offsetting any benefits of successful product introductions and potentially leading to challenges in managing 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 demand for existing products in advance of new product introductions, and we may experience a slowdown in 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 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 models sold or leased; • 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; • 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, goods imported from Mexico where we manufacture a majority of our instruments 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 . 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~~ **surgical** ~~System~~ **system** and our other products represent a fundamentally new way of 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. We expect that there will continue to be a learning process involved for patient 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 Legislation and Policy May Have a Material Adverse Effect on Our Business, Financial Condition, or Results of 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. **These limits** ~~This rule has had and may continue to~~ have **significantly** ~~a material negative impact~~ **impacted** ~~on our~~ **the number of** procedures performed **and have impacted our instruments and accessories revenue** in ~~the~~ **those** ~~Hunan province~~ **provinces** . **Companies providing** ~~In addition to the Hunan province, the Hainan province (an island province of China) recently announced a policy to implement almost identical limits on what hospitals can charge patients for surgeries using~~ 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 ~~other~~ **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 ~~, AS A RESULT, INCUR ADDITIONAL UNFORESEEN COSTS, 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 injury to, or death of, 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, ~~which can include~~ **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 ~~difficulties to persist in the foreseeable future~~ **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** ~~Prices of such materials~~ have **strategic relationships with a number of key distributors** ~~also increased,and global supply has become significantly constrained due to the increased demand~~ for **the sale and** ~~materials,including semiconductors,to support expansion of server~~ - **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** ~~cloud~~ - **could** ~~networks~~ **be adversely affected.In addition,we may be named** as a ~~greater proportion~~ **defendant in lawsuits against our distributors related to sales or service** of **our products performed by** ~~the~~ **them** ~~global population worked remotely,the introduction of 5G,and the continued electrification of vehicles~~ . **Refer to our risk factor titled "** We **are subject** ~~engage in activities~~ to **litigation** ~~seek to mitigate such supply disruptions by~~ , **investigations** ~~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,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~~ **legal proceedings relating to our products** , ~~we~~ **customers,competitors,and government regulators that** could **materially** ~~also fail to meet product demand,which would~~ adversely ~~impact~~ **affect** our ~~business,~~ financial condition, **divert management' s attention,and harm** ~~or~~ **our** ~~results~~ **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 ~~operations~~ **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,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 associated with public health crises and outbreaks of epidemic,pandemic,or contagious diseases,such as the current outbreak of a novel strain of coronavirus (COVID- 19).To date,COVID- 19 has had,and may continue to have,an adverse impact on our operations,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 supply chain issues that could impact their ability to provide patient care.Due to these impacts and measures,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 the COVID- 19 pandemic,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, ~~or~~ clearances from the FDA **,** or ~~foreign~~ 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.WE ~~ARE SUBJECT TO LITIGATION,INVESTIGATIONS,AND OTHER LEGAL PROCEEDINGS RELATING TO OUR PRODUCTS,OUR CUSTOMERS,OUR 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~~ 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 indemnify our directors and officers for 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 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. ~~IF WE LOSE KEY PERSONNEL~~ **INFORMATION TECHNOLOGY SYSTEM FAILURES, CYBERATTACKS,** OR ~~ARE UNABLE 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 clearance for the remanufacturing of any instruments for use with a da Vinci X or da Vinci Xi Surgical System,but we understand that the FDA has granted 510 (k) clearance to one company for the remanufacturing of an EndoWrist instrument used with our da Vinci S and da Vinci Si Surgical Systems.While our sales arrangements with customers generally prohibit the use of unauthorized and unapproved instruments and accessories that lack FDA clearance or other applicable regulatory approval or certification with 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.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.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,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. **The risk of a security breach or a disruption has generally increased in number,intensity,and sophistication.Techniques used to compromise or sabotage systems,including the use of advanced technologies,such as machine learning or artificial intelligence,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** ~~use encryption and authentication technologies~~ to ~~secure~~

~~the transmission~~ **detect,contain,** and ~~storage of~~ **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 ~~,which may,in turn,be used to access our~~ - **or otherwise** ~~information technology systems.As a result of the COVID- 19 pandemic,we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely,which may create additional opportunities for cybercriminals to exploit vulnerabilities.In addition,unauthorized persons may~~ attempt to hack into our ~~products or~~ **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 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 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** ~~have programs in place to detect,contain,and respond to data security~~ **cybersecurity** ~~incidents,~~ **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 ~~make ongoing improvements to our information- sharing products in order to minimize vulnerabilities,in accordance with industry and regulatory standards.However,because the techniques used to obtain unauthorized access to or steal personal information or intellectual property,or sabotage systems containing personal information or intellectual property,change frequently and may originate from less regulated and remote areas of the world and be difficult to detect,we may not be able to anticipate and prevent these intrusions or mitigate them when and if they occur.Even if identified,we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls,avoid detection,and remove or obfuscate forensic evidence.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. ~~Globally,attacks are expected to continue accelerating in both frequency and sophistication with increasing use of tools and techniques that are designed to circumvent controls,avoid detection,and remove or obfuscate forensic evidence,all of which hinders our ability to identify,investigate,and recover from incidents.~~ Furthermore, ~~due~~ **we may implement changes** to **information technology systems** ~~the political uncertainty involving Russia and Ukraine,there is also an increased likelihood that the tensions could result in cyberattacks or cybersecurity incidents~~ that could **have significant** ~~either directly or indirectly impact~~ **impacts on** our **manufacturing,sales,and finance functions,among other teams.These impacts may include (i)** ~~operations~~ **operational** ~~.Any attempts~~ **disruptions resulting from the slow adaptation of the new information technology systems** by ~~cyber- attackers~~ **employees,whether due** to ~~disrupt~~ **inadequate training** ~~our~~ - **or** ~~services~~ **resistance to change,** or **data loss during the transition to the updated** information technology ~~systems~~ - **system,including critical customer data,or**

improper planning leading to the loss of essential software features needed ~~or~~ **for** ~~the services~~ **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 ~~systems of~~ **fail to meet regulatory requirements** ~~our~~ - **or** ~~third- party service providers,~~ **industry standards;and (vi)** strategic **risks** ~~partners,and other contractors or consultants,~~ if ~~successful,could harm our business,result in~~ the **technology implementation fails** ~~misappropriation of funds,be expensive~~ to **deliver the expected benefits** ~~remedy,and damage our reputation or brand~~ .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. **THE FAILURE** ~~OUR BUSINESS IS SUBJECT~~ TO ATTRACT AND RETAIN ~~OTHER~~ **KEY** PERSONNEL ~~,~~ **COULD HARM** OUR ABILITY TO COMPETE ~~WILL BE HARMED~~ , AND ~~INCREASES~~ **CHANGES** IN **OUR EXISTING** LABOR ~~COSTS~~ **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, and robotics engineers. Attracting and retaining qualified personnel **is** ~~will be~~ 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 ~~among technology and healthcare companies~~ . Additionally, as a result of ~~recent declines~~ **the volatility** in our stock price, certain long- term incentive benefits, such as **equity grants** ~~recently issued stock options~~ , 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, ~~and~~ retention benefits, ~~which may result from higher inflationary environments~~ **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 ~~continuing~~ **remaining** impact of ~~the~~ COVID- 19 ~~pandemic~~ , 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 ~~and earning loyalty~~ **, 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 results of operations and financial condition. Moreover, if we fail to attract, motivate, or retain personnel, or 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. ~~Many of~~ **We could also be subject to union or council efforts to organize** our employees ~~have worked remotely during the COVID- 19 pandemic, which makes it challenging to maintain or enhance our culture~~ . **These organizational efforts** ~~While we are exploring ways to improve the employee experience~~ , ~~regardless of whether~~ **if successful, decrease operational flexibility** ~~an~~ **and could adversely affect** ~~employee is working from home, fully on- site, or~~ **our** ~~in a hybrid fashion~~ **operating efficiency. In addition** , ~~the impact this will have on~~ our **response** ~~corporate culture, innovation, collaboration, and ability~~ to ~~attract~~ **any organizational efforts could be perceived negatively** and **harm our business and** ~~retain~~ **reputation** ~~talent is uncertain~~ . 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~~ **surgical** ~~System~~ **system** , its 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 EXPERIENCE LONG AND VARIABLE CAPITAL SALES CYCLES AND SEASONALITY IN OUR BUSINESS, WHICH MAY CAUSE FLUCTUATIONS IN OUR FINANCIAL RESULTS. The 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 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 using da Vinci ~~Surgical~~ **surgical** ~~Systems~~ **systems** . Further, the introduction of new products could adversely impact our sales 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 capital sales cycles and, therefore, the exact timing of capital sales. Historically, our sales of da Vinci ~~Surgical~~ **surgical** ~~Systems~~ **systems** have tended to be heavier in the fourth quarter and lighter in the first quarter, as hospital budgets are reset. We have experienced procedure growth for a number of benign conditions, including ~~hysterectomies, sacrocolpopexies,~~ 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 in the first and third quarters of the year and higher procedure volume 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 . NEW PRODUCT DEVELOPMENTS AND INTRODUCTIONS MAY...... access or regulatory compliance in such cases . WE OFFER ALTERNATIVE CAPITAL ACQUISITION APPROACHES AND, AS A RESULT, 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 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. While leases ~~and~~ **, 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** ~~or~~ **our profitability on those transactions. Moreover, the usage of those systems 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, if customers** return or terminate ~~leases~~ **these arrangements** prematurely, it could have a material adverse effect on our business, financial condition, or result ~~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,service,and business operations to limit personal information processing to within individual countries could increase our operating costs significantly.ONGOING AND POTENTIAL FUTURE GLOBAL CONFLICTS COULD ADVERSELY AFFECT OUR BUSINESS,FINANCIAL CONDITION,OR RESULTS OF OPERATIONS.~~ In February 2022,Russian military forces launched a military action in Ukraine,and sustained conflict and disruption in the region has continued **.The length,impact,and outcome of this ongoing military conflict 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 cyberattacks and espionage** .Russia' s military actions against Ukraine have led to 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 retaliation against new international sanctions and as part of measures to stabilize and support the volatile Russian financial and currency markets,the Russian authorities also imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia,imposed various restrictions on transacting with non- Russian parties,banned exports of various products,and imposed other economic and financial restrictions.The situation is rapidly evolving,and additional sanctions by Russia on the one hand,and by the other countries on the other hand,could adversely affect the global economy,financial markets,energy supply and prices,certain critical materials and metals,supply chains,and global logistics and could adversely affect our business,financial condition,or results of operations. ~~Separately,~~ 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 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 the U. S. Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors 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 limits, under a systemic risk exception, future adverse developments with respect to specific 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 Intuitive Ventures fund ~~plans to invest~~ **invests** 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. 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 ~~THE ONGOING ARMED CONFLICT BETWEEN RUSSIA AND UKRAINE COULD~~ ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, OR RESULTS OF OPERATIONS. In February 2022, Russian military forces...... condition, or results of operations. We are **subject** ~~actively monitoring the situation in Ukraine and Russia and assessing its impact 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 **taxes** ~~support our operations. We have no way to predict the progress or outcome of the military conflict~~ in ~~Ukraine or its impacts in Ukraine, Russia, Belarus, Europe, or~~ the U. S. ~~The extent~~ and ~~duration of the military action, sanctions,~~ other **jurisdictions around the world. Tax rates in** ~~consequences, such as Russia imposing restrictions on transactions or banning the~~ **these jurisdictions may** ~~export of energy products, including natural gas, and the resulting market disruptions could~~ be **subject to** significant **change due to** ~~and could potentially have substantial impact on the global economy~~ **economic** ~~and our business for an~~ **and /** ~~unknown period of time. Impacts to our~~ - **or political conditions** ~~business may include, but are not limited to, procedures performed, demand for our products, and ability to spend on capital equipment and healthcare in general~~ . ~~Any such disruption~~ **A number of other factors** may also ~~magnify the~~ impact ~~of other risks described. WE MAY ENCOUNTER MANUFACTURING PROBLEMS OR DELAYS THAT COULD RESULT IN LOST REVENUE. Manufacturing our products is a complex process. We (or~~ **our future effective tax rate** ~~our critical suppliers) may encounter difficulties in scaling up or maintaining production of our products~~ , including: • ~~problems involving production yields~~ **the jurisdictions in which profits are determined to be earned and taxed** ; • ~~quality control and assurance~~ **the resolution of issues arising from tax audits with various tax authorities** ; • ~~component supply shortages~~ **changes in the valuation of our deferred tax assets and liabilities** ; • ~~import~~ **increases in expenses not deductible** ~~or~~ **for tax purposes** ~~export restrictions on components~~ , ~~materials, or technology~~ **including write- offs of acquired intangibles and impairment of goodwill in connection with acquisitions** ; • ~~shortages~~ **changes in the availability** of ~~qualified personnel~~ **tax credits, tax holidays, and tax deductions** ; ~~and~~ • ~~compliance with state, federal, and foreign regulations. If demand~~ **changes in share- based compensation; • changes in tax laws** ~~for~~ - **or the interpretation** ~~our products exceeds our manufacturing capacity, we could develop a substantial backlog~~ of ~~customer orders~~ **such tax laws; and • changes in generally accepted accounting principles** . **We** ~~If we~~ are unable to ~~develop~~ **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** ~~or~~ **our** ~~maintain larger~~ **business, including changes resulting from the base erosion and profit shifting (" BEPS ") project undertaken by the Organization for Economic Co** - ~~scale manufacturing capabilities~~ **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 %. 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 ~~build~~ **have announced plans to adopt,** new **tax laws to align** ~~manufacturing capabilities or facilities on schedule or within~~ -- **with** ~~budget, our ability to generate revenue and maintain profit margins as expected will be limited and our reputation in~~ the ~~marketplace~~ **global minimum tax. These changes** could **increase tax uncertainty and** ~~be damaged, all of which~~ 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 GOVERNMENT AGENCIES OR NOTIFIED BODIES ~~CAUSED BY FUNDING SHORTAGES OR GLOBAL HEALTH CONCERNS~~ COULD HINDER THEIR ABILITY TO HIRE, RETAIN, OR DEPLOY ~~KEY LEADERSHIP AND OTHER~~ PERSONNEL, OR OTHERWISE PREVENT 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, 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 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, in response to the global COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, ~~the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic, and~~ any resurgence of the virus or emergence of new variants may lead to further inspectional **or administrative** delays ~~. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID- 19 pandemic~~ . If a prolonged government shutdown occurs, or if global health concerns ~~continue to~~ prevent the FDA, other regulatory authorities, or notified bodies from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, other regulatory authorities, or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. 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** ~~While several notified bodies have been designated~~ **designation process** , **which is significantly stricter under the new regulation, has experienced considerable delays due to** the COVID- 19 pandemic ~~has~~ **. Despite a recent increase in designations, the current number of notified bodies designated under the new Regulation remains** significantly ~~slowed down~~ **lower than** ~~their~~ -- **the number of notified bodies** ~~designation~~ **designated under** ~~process, and~~ the **previous regime. The** current designated notified bodies are **, therefore,** facing a **backlog** ~~large number~~ of requests ~~with the new regulation~~ , **and** ~~as a consequence of which~~ review times have lengthened. ~~Unless additional transitional measures are implemented, this~~ **This** situation could impact our ability to grow 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) 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 ~~operations~~ .CLIMATE CHANGE ~~AND~~ **,** NATURAL DISASTERS **,** OR OTHER EVENTS BEYOND OUR CONTROL COULD DISRUPT OUR BUSINESS ~~AND~~ **,FINANCIAL CONDITION,OR** ~~RESULT~~ **RESULTS** ~~IN LOSS~~ OF **OPERATIONS** ~~REVENUE OR HIGHER EXPENSES~~ .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.Physical risks associated with climate change are subject to increasing societal,regulatory,and political focus in the U.S.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 ~~the~~ **our** regulatory obligations.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 ~~.CHANGES~~ . CONTINUED 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...... in our future effective tax rate could 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; • 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 ~~which~~ **that** suggest the same; and • the reporting of corrections 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~~ **surgical** ~~System~~ **system** 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 or that we have compiled adequate information to support the safety and efficacy of using the da Vinci ~~Surgical~~ **surgical** ~~System~~ **system** for all such specific procedures. From time to time, we modify our products, including the hardware and software in the da Vinci ~~Surgical~~ **surgical** ~~System~~ **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 and / or require us to obtain 510 (k) clearance or other FDA marketing authorization for any modification to our products. We may be prohibited from marketing the modified device until such marketing authorization is granted. 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, and Japan, among others. 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. A PMA is typically a much more complex, lengthy, and burdensome application than a 510 (k) or a 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. In some cases, such studies may also be required to support a 510 (k) application or a de novo classification request. 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 February 23, 2022, the FDA issued a proposed rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization (" ISO ") standards. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business. 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. Moreover, the disruptions caused by the COVID- 19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our planned and ongoing~~ 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. 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 ~~timeframe~~ **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 results. IF OUR MANUFACTURING FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE, OR OTHER MANUFACTURING 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 RESULT IN SIGNIFICANT PRODUCT DELIVERY DELAYS AND LOST REVENUE. Our manufacturing facilities are subject to periodic inspection by regulatory authorities and 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 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 moving targets related to the regulatory landscape is in the EU; more specifically, the regulation of medical devices has recently evolved. The EU Medical Devices Regulation, which repeals and replaces the EU Medical Devices Directive, became applicable on May 26, 2021. **In accordance with its recently extended transitional provisions, both (i)** ~~Devices~~ **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 ~~May 26~~ **December 31** , ~~2025~~ **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 ~~. In particular, the certificate in question must still be valid~~ . 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, ~~market surveillance~~ **clinical periodic review report** , and vigilance requirements. 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. In January 1999, further to their certification by our notified body, Presafe, we affixed the CE mark to our da Vinci ~~Surgical~~ **surgical** ~~System~~ **system** and EndoWrist instruments, attesting compliance with 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 ~~by the end of the validity of our certificates granted under the former EU Medical Devices Directive, which may not exceed the transitional period currently set forth in the EU Medical Devices Regulation of May 26, 2024~~ , this would prevent us from selling our products in the EU and EEA. **Should we not gain such certification** ~~However, under recently proposed draft legislation issued~~ by the ~~European Commission, this date could be extended to~~ **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 ~~to~~ 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 date, we received approvals from the Japanese Ministry of Health, Labor and Welfare for our da Vinci ~~S,~~ Si, Xi, X, and SP ~~Surgical~~ **surgical** ~~Systems~~ **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 capital sales in China are subject to importation authorizations and purchasing tender processes. In ~~October 2018~~ **June 2023** , the China National Health Commission published ~~on its official website~~ the **14th five- year plan** quota for major medical equipment to be ~~imported and~~ sold in China ~~through~~ **on its official website. Under the** ~~2020~~ **2023 Quota** ~~. After an adjustment notice was published in the third quarter of 2020 (ref. NHC Financial Notice [2020] 315)~~ , the government will allow for the ~~total~~ sale of ~~225~~ **559** new ~~Endoscopic Surgical Instrument Control Systems (~~ surgical robots ~~)~~ into China, which could include da Vinci ~~Surgical~~ **surgical** ~~Systems~~ **systems** as well as surgical systems introduced by others. 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 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 ~~was enacted~~ **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 ~~2031~~ **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** ~~was signed into~~ 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 ~~(" HTA ")~~ , amending Directive 2011 / 24 / EU, was adopted. ~~This~~ **While the** ~~regulation~~ **Regulation** ~~, which~~ entered into force in January 2022, **it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once 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 ~~provides~~ - **provide** the basis for cooperation at the EU level for joint clinical assessments in these areas. **It** ~~The regulation foresees a three- year transitional period and~~ will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the ~~most~~ **highest** potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical, 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 ~~also~~ 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** , ~~among~~ **physicians, or** other **healthcare professionals** ~~things, payments or other remuneration that could be considered to induce hospitals, physicians, or other potential purchasers of our products~~ 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 ~~and state~~ healthcare programs, such as Medicare ~~and~~ **,** Medicaid **,** and ~~any~~ 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 ~~jurisdiction~~ **jurisdictions** . ~~The~~ **We must comply with the** federal civil and criminal false claims laws, including the federal ~~civil~~ False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, 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~~ **False** ~~claim act~~ **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 ~~for non- compliance~~ . 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 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 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 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 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. 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 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 ~~2020~~ **2021** , the adjusted closing price of our common stock reached a high of $ ~~272~~ **365** . ~~70~~ **42** and a low of $ ~~122~~ **228** . ~~58~~ **30** ; during ~~2021~~ **2022** , it reached a high of $ ~~365~~ **360** . ~~42~~ **00** and a low of $ ~~228~~ **183** . ~~30~~ **06** ; and, during ~~2022~~ **2023** , it reached a high of $ ~~360~~ **354** . ~~00~~ **93** and a low of $ ~~183~~ **224** . ~~06~~ **75** . 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.