Risk Factors Comparison 2024-03-21 to 2023-03-02 Form: 10-K

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Our risk factors are grouped into the following categories: (1) Risks Related to the Operation of our Business; (2) Risks Related to Our Status as a Public Company; (3) Risks Related to Protection of our Intellectual Property; **and** (4) Risks Related to the Regulation of our Business ~~; and (5) General Risk Factors~~ . We have a history of operating losses, and we may not be able to achieve or sustain profitability. We have a limited operating history. We are not profitable and have incurred losses since our inception. Our accumulated deficit was $ ~~860~~ **939** . ~~9~~ **4** million **,** and our working capital was $ ~~76~~ **23** . ~~5~~ **8** million as of December 31, ~~2022~~ **2023** . We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we continue to develop and commercialize our products. We will continue to incur research and development and general and administrative expenses related to our operations, and sales and marketing expenses to support our commercial activities ~~, as restructured~~ . Even if we are successful in reducing our expenses or achieving profitability in the future, we may not be able to sustain profitability in subsequent periods. Our recurring operating losses and negative cash flows raise substantial doubt about our ability to continue as a going concern. We will need additional financing to execute our business plan and fund our operations. Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources in the foreseeable future, particularly as we increase our research and development spending as we develop and seek regulatory approval for the LUNA System and enhancements to our digital surgery and Performance- Guided Surgery product offerings. Management has concluded that substantial doubt exists about our ability to continue as a going concern as a result of anticipated capital needs in conjunction with past recurring losses and an accumulated deficit. **As** ~~Our independent registered public accounting firm also included an explanatory paragraph in its report on our consolidated financial statements as~~ of ~~and for the year ended~~ December 31, ~~2022~~ **2023** ~~with respect to this uncertainty~~ **, our accumulated deficit was $ 939. 4 million, and our working capital was $ 23. 8 million** . We believe that our existing cash, cash equivalents ~~,~~ **and** short ~~- term investments and long~~ - term investments, together with cash received from product, service, and lease sales will be sufficient to meet our anticipated cash needs into **early June** ~~the first quarter of~~ 2024. ~~We~~ **However, we** will need additional financing to implement our next generation products strategy. ~~We believe we have cash~~ **Management' s plans to obtain additional resources for the Company may include additional sales of equity, traditional financing, such as loans, entry into strategic collaborations, entry into an out- licensing arrangement or provision of additional distribution rights in some or all of its markets. Management cannot provide any assurance that the Company will be successful in accomplishing any or all of its plans. If sufficient funds are not received** on **a timely basis, the Company would then need to reduce costs further** ~~hand~~ - **and /** ~~to sustain our~~ - **or pursue a plan to license or sell its assets, seek to be acquired by another entity, cease** operations ~~into the first quarter of 2024,~~ and **/ or seek bankruptcy protection** ~~also believe we will need to raise capital in order to implement the LUNA System program~~ . Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing. Our strategic focus, on delivering tools..... condition, and results of operations. We will require substantial additional funding to advance our current plans. We are focused on our development efforts for our products, including the LUNA System and enhanced digital solutions, and commercialization of the Senhance System, ISU and other products, as well as market development for our products and other research and development activities. We expect increased research and development spend associated with the development of the LUNA System, next generation versions of the ISU and enhanced digital solutions, putting additional pressure on funding requirements as we advance through regulatory processes and commercialization, if our R & D efforts are successful. We intend to advance multiple additional products through clinical and pre- clinical development in the future. We will need to raise additional capital in the future in order to fund these priorities and achieve our business objectives **. Any delays in raising additional capital will delay the current anticipated timelines for development and commercialization** . We cannot assure you that we will be successful in obtaining additional financing in the future on terms acceptable to the Company or at all. Until we generate a sufficient amount of revenue to finance our cash requirements, which may never occur, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution; and debt financing, if available, may involve restrictive covenants that limit our operations. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our products or grant licenses on terms that may not be favorable to us. Our strategic focus,on delivering tools and assistance to provide Performance- Guided Surgery opportunities,may not result in the growth of our business in the timeline we envision or at all.On February 23,2021,we announced a strategic focus on providing clinical intelligence to surgeons to provide Performance- Guided Surgery opportunities.We believe that the Senhance System,which digitizes the interface between the surgeon and the patient in laparoscopic surgery,can also be used,with our Augmented Intelligence offerings,to provide real- time clinical data throughout the entire surgical experience,assist in removing elements and factors that contribute to surgical variability and reduce complications.Our efforts to communicate and implement this strategy with hospitals,surgery centers and surgeons may take longer than we anticipate,may not be as successful as we contemplate,and may not result in a meaningful ~~increase~~ **improvement** in our business or financial condition.In order to compete successfully within the surgical robotics **and digital surgery** industry,we need to continue to evolve our robotic

surgery products **and our digital surgery offerings** ~~,including the innovations associated with assets we acquired~~ .Failure to develop,obtain regulatory approval for and **successfully** commercialize such developments could have a material adverse effect on our business and financial position.In order to compete successfully within the highly competitive surgical robotics industry,we need to continue to advance and innovate our robotic surgery products,including the innovations associated with the assets we acquired from MST in 2018.Our focus currently is on harnessing the image technology acquired in the MST acquisition to advance the intelligence of our products through the ISU to provide meaningful real- time Augmented Intelligence to surgeons. **In addition,we entered into an agreement with NIVDIA and need to successfully harness the additional opportunities this agreement presents to us.** We have developed and received CE Mark in Europe and FDA clearance in the U.S.for articulating instruments.These assets are also vital to our Performance- Guided Surgery strategy.If we fail to continue to develop such innovations,or fail to obtain regulatory approval or clearance for or to successfully commercialize such innovations,such failure could have a material adverse effect on our business and financial position.We are also focused on ~~commercializing~~ ----- **commercial activities related to** our ISU as a vital part of our Performance- Guided Surgery initiative.If we are not successful in commercializing the **ISU,including a standalone** ISU,our business could be materially adversely affected.Companies such as us rely on innovation and new product development to attract and retain customers.Such development efforts take time,are expensive,and there is no certainty that we will be successful in commercializing the ISU,developing the LUNA System,or receiving regulatory clearances and approvals,on a timely basis,if at all.If we are not successful in our development efforts,such failure will have a material adverse effect on our business and financial position. ~~22We~~ **We are focusing our development efforts on developing the LUNA System.If our development efforts are not successful,or if the LUNA System is not a commercial success,our business opportunities and financial position will be adversely affected.The primary focus of our product development efforts are focused on our next generation robotic LUNA System.Development of a robotic system is difficult,time- consuming and expensive.We could suffer development setbacks,not meet our projected development schedule,become unable to finance the needed development efforts,fail to receive necessary regulatory clearance or approvals,or encounter difficulties in the manufacturing process.In addition,even if we do develop the LUNA System and receive the necessary regulatory clearances and approvals,we may be unable to successfully commercialize the LUNA System.If any of these risks occur,our business and financial position will be adversely affected.The success of the LUNA System development efforts will be impacted by the results of the regulatory pathway.We believe the regulatory pathway for the LUNA System will follow the 510 (k) clearance pathway applicable to our other products.If the FDA determines that the LUNA System is " not substantially equivalent " to a previously cleared device,we might then need to fulfill the more rigorous PMA requirements,or request a risk- based classification determination for the device in accordance with the " de novo " process.Either alternative pathway would add significant time to our pursuit of FDA approval of the LUNA System,which could have a material adverse effect on our business and financial position.We** may not be successful in realizing benefits from our collaboration agreements.We are collaborating with Google on further developing the Asensus Cloud as a key component of our LUNA System product offerings,and ~~have signed an MOU with KARL STORZ to increase sales of our ISU and to develop instruments and other technologies with them.We may not be successful in completing the definitive~~ agreements with ~~KARL STORZ~~ **NVIDIA and Flex related to** ~~or~~ **our ISU and LUNA System development efforts** ~~realizing the benefits of these collaborative programs~~ .If we are not successful **in capitalizing on these collaborations** ,our reputation and our operations and financial condition may be harmed. ~~The coronavirus (COVID- 19) pandemic has negatively impacted our operations.We have facilities located in the United States,Israel,Japan,and Italy.All of our facilities are in locations that are subject to,or have been subject to,travel restrictions,stay- at- home or shelter- in- place orders,or return- to- work on a hybrid basis.Our Senhance Systems are manufactured at a contract manufacturing facility in Milan.A variety of travel restrictions,caused delays in our product installation and training activities in 2022.Elective surgeries have also been curtailed a number of times during variant surges in 2022 in various parts of the globe.Although such procedures have recommenced in large part,the limits on elective procedures significantly impacted our ability to place our Senhance Systems,provide training,and increase the use of the Senhance Systems in place.It is uncertain whether elective surgeries will continue to be negatively impacted or halted again in the future by a resurgence of COVID- 19 cases in any of these jurisdictions.The global spread of COVID- 19 and the various attempts to contain it continue to create significant volatility,uncertainty and economic disruption.The full extent to which the COVID- 19 pandemic and the various responses to it impacts our business,operations and financial results continues to depend on numerous factors that we may not be able to accurately predict,including:the duration and scope of the pandemic,including new variants;governmental,business and individuals' actions that have been and continue to be taken in response to the pandemic;the availability and cost to access the capital markets;the decline in elective surgical procedures;the effect on our customers and customer demand for Senhance Systems and the ability to provide training services;disruptions or restrictions on our employees' ability to work and travel;and shortages of certain supplies and materials.In addition,any preventative or protective actions that governments implement or that we take in respect of COVID- 19,such as travel restrictions or stay- at- home orders,may interfere with the ability of our employees,vendors and contract manufacturers to perform their respective responsibilities and obligations relative to the conduct of our business.Such results could have a material adverse effect on our operations,business,financial condition,results of operations,or cash flows.We believe the COVID- 19 pandemic,including emerging variant strains of the virus,will continue to negatively impact our operations and our ability to implement our market development efforts,which will have a negative effect on our financial condition.There is a risk that government actions will not be effective at containing further COVID- 19 outbreaks,including from variants,and that government actions,including the orders and restrictions described above,that are intended to contain the spread of COVID- 19 will have a devastating negative impact on the world economy at large,in which case the risks to our sales,operating results and financial condition described herein would be elevated significantly.We are currently highly dependent on a single product,the Senhance System.~~We cannot

give any assurance that the Senhance System can be successfully commercialized.We ~~are currently highly dependent on the Senhance System,which is FDA cleared for sale in the United States,CE Marked for sale in the European Union and other countries,registered for sale in the Russian Federation,and approved for sale and reimbursement in Japan.We~~ began our selling efforts for the Senhance System in the fourth quarter of 2015 in Europe,in the fourth quarter of 2017 in the United States,in the second quarter of 2018 in Asia and,through distributors in the Russian Federation in 2021.We have had limited commercial success to date ~~,particularly in 2019 and 2020~~ .We have determined to focus our energies on market development and increased usage of the Senhance Systems that have been purchased and placed,as well as on our Performance- Guided Surgery strategy.We cannot assure you that we will be able to successfully improve the commercialization of the Senhance System,for a number of reasons,including,without limitation,failure in our market development and sales efforts,the long sales cycle associated with the purchase of capital equipment,and the potential introduction by our competitors of more clinically effective or cost- effective alternatives.In addition,we are now more focused on developing the LUNA System than ~~focusing~~ on continued commercial success ~~with~~ **of** the Senhance System.We cannot assure you that we will be successful in continuing to grow utilization of the Senhance System and the ISU year over year.While we believe Performance- Guided Surgery and our other tools available ~~to~~ **can** assist the laparoscopic surgeon **to** perform successful surgeries,it is time- consuming to educate and train physicians and educate hospitals on the benefits of use of the Senhance System with the ISU.If we cannot continue to grow our procedure volume year over year,our business and financial condition will be adversely affected. ~~23We have de- emphasized~~ **If we fail to attract and retain key management and professional personnel,we may be unable to successfully commercialize or develop our products.We will need to effectively manage our operational,** sales ~~of~~ **and marketing,development and** ~~the~~ **other resources in order to successfully pursue our commercialization and research and development efforts for our existing and future products.Our success depends on our continued ability to attract,retain and motivate highly qualified personnel.If we are not successful in retaining and recruiting highly qualified personnel,our business may be harmed as a result.We use distributors to sell our** Senhance ~~System~~ **Systems** ~~,which occurs now only in areas in which our distributors and certain areas in Europe and Japan~~ .Purchase of a surgical robotic system such as the Senhance System represents a capital purchase by hospitals and other potential customers,which is a time- intensive process involving ~~adoption~~ **buy- in** by surgeons and approval of the capital purchase by administration ~~.We are also expanding the potential market for robotic surgical systems with our focus on laparoscopic surgery.Such expansion requires a different sales and marketing approach than a focus on open procedures.We have found that sales are extremely difficult and take substantial effort.In late 2019,we began leasing Senhance Systems to hospitals with lease terms ranging from twelve to twenty- four months or more.We cannot assure you that these lease arrangements will lead to longer term placements or result in sales of our Senhance System~~ .We use distributors and sales agents in a number of geographic locations where we do not have sales personnel.We have procedures in place ~~to~~ **that** require our distributors and sales agents to comply with applicable laws and regulations governing the sales of medical devices in the jurisdictions where they operate.Failure to meet such requirements could subject us to financial penalties or the suspension or termination of ~~the~~ **our** ability to sell ~~our~~ products in such ~~jurisdiction~~ **jurisdictions** .The surgical robotics and digital surgery industries are increasingly competitive,which can negatively impact our commercial opportunities.The medical device industry is highly competitive,and we face significant competition from ~~many~~ companies that are researching and marketing products ~~designed~~ to address minimally invasive and robotic- assisted surgery,including new entrants in the ~~competitive~~ market.We are currently commercializing the Senhance System in the United States with FDA 510 (k) clearance,in Europe which accepts a CE Mark,the Middle East,the Commonwealth of Independent States,and selected countries in Asia.We face significant competition in such markets.Many of our competitors,including Intuitive Surgical,have significantly greater financial,manufacturing,marketing and product development resources than we do.Some of the medical device companies **that** we **do** ~~compete with~~ or expect to compete with include Medtronic plc,Intuitive Surgical Inc.,Vicarious Surgical,Inc.,Momentis Surgical,Distalmotion SA, ~~and~~ CMR Surgical Ltd.,Activ Surgical,Inc.,Theator Surgical,CareSyntax Inc.and a number of **MIS** ~~minimally invasive surgical device~~ and robotic surgical device manufacturers and providers of **solutions** ~~products and therapies~~ that are designed to reduce the need for or attractiveness of surgical intervention.In addition,many ~~other~~ universities and private and public research institutions are or may become active in research involving surgical devices for **MIS** ~~minimally invasive~~ and robotic- assisted surgery.We are also expanding the potential market for robotic surgical systems with our focus on laparoscopic surgery **which** ~~.Such expansion~~ may lead to additional competition with companies with ~~sufficiently higher~~ **substantially greater** resources than ours.We believe that our ability to successfully compete will depend on,among other things:the efficacy,safety and reliability of our products;our ability to commercialize and market our cleared or approved products;the completion of our development efforts and receipt of regulatory clearance or approval for instruments and accessories to support the use of the Senhance System;the **lower** cost of ownership and use of our products in relation to alternative devices;the timing and scope of regulatory clearances or approvals,including any expansion of the indications for use for our products;whether our competitors substantially reduce the cost of ownership and use of an alternative device;our ability to protect and defend intellectual property rights related to our products;our ability to have our partners manufacture and sell commercial quantities of any cleared or approved products to the market; ~~our ability to adapt to changes in the regulatory environment;~~ the effectiveness of our sales and marketing efforts;and acceptance of future products by physicians and other healthcare providers **.We have also seen a trend in the market for large medical device companies to acquire,invest in,or form alliances with smaller companies in order to diversify their product offerings and participate in the digital health space.We may find increased competition from other companies,many better capitalized than we are** .If our competitors market products that are more effective,safer,easier to use or less expensive than our products or future products,or that reach the market sooner than our products,we may not achieve commercial success.In addition,the medical device industry is characterized by rapid technological change.It may be difficult for us to stay abreast of the rapid changes in each technology.If we fail to stay at the forefront of technological change,we may

be unable to compete effectively.Technological advances or products developed by our competitors may render our technologies or products obsolete or less competitive.We anticipate that the highly competitive surgical robotics environment can lead our competitors to attempt to slow or derail our commercial progress.We are using our best efforts to enter the commercial markets effectively ~~and efficiently~~ while maintaining compliance with all regulatory and legal requirements.Responding to the actions of our competitors ~~will require the attention of our management and~~ may distract the management team from its focus on our commercial operations and lead to increased costs of commercialization,which could have a negative impact on our financial position.We also anticipate that the competitive ~~surgical robotics and digital surgery~~ environments will become more intense because of increased consolidation by companies in the healthcare industry looking to achieve cost reductions.Such consolidation may have an adverse effect on our business operations. ~~24Use~~ -- **Use** of our Senhance System requires training for surgeons,and inadequate training may lead to negative patient outcomes,which could harm our business,financial condition,and results of operations.The successful use of our Senhance System depends in part on the training and skill of the surgeon performing the procedure and his or her comfort level with the use of a robotic device.We provide training and **proctoring,as well as Senhance Connect,that allows us to provide real- time guidance as desired.We cannot be certain that all of the surgeons that use our Senhance System have received and completed sufficient training.If a surgeon uses our Senhance System incorrectly,or without adhering to or completing all relevant training,their patients could be negatively affected.Adverse safety outcomes that arise from improper or incorrect use of our Senhance System may limit adoption of our Senhance System,which could harm our sales,business,financial condition,and results of operations.Issues relating to the use of artificial intelligence and machine learning in our offerings could adversely affect our business and operating results.We integrate artificial intelligence,AI,and machine learning in our products.Issues relating to the use of new and evolving technologies such as AI and machine learning may cause us to experience brand or reputational harm,competitive harm,legal liability,and new or enhanced governmental or regulatory scrutiny,and we may incur additional costs to resolve such issues.As with many innovations,AI presents risks and challenges that could undermine or slow its adoption,and therefore harm our business.For example,perceived or actual technical,legal,compliance,privacy,security,ethical or other issues relating to the use of AI may cause public confidence in AI to be undermined,which could slow our customers' adoption of our products and services that use AI.In addition,litigation or government regulation related to the use of AI may also adversely impact our and others' abilities to develop and offer products that use AI,as well as increase the cost and complexity of doing so.Further,market demand and acceptance of AI technologies are uncertain,and we may be unsuccessful in our product development efforts.** Negative publicity, whether true or not, concerning us or our products could reduce market acceptance of our products ~~and could result in decreased demand for the Senhance System~~ . There have been social media and other publications regarding us ~~and the Senhance System~~ published from time to time since we started selling the Senhance System. Negative media and social media coverage, whether true or not, concerning our products or us could reduce market acceptance of **our products** ~~the Senhance System~~ and increase volatility in our stock price. We are subject to risk as a result of our international manufacturing operations. Because most of our products are manufactured at third- party facilities located in Europe, Israel and Singapore, our operations are subject to risk inherent in doing business internationally. Such risks include the adverse effects on operations from corruption, war, international terrorism, civil disturbances, political instability, government activities such as border taxes and renegotiation of treaties, deprivation of contract and property rights and currency valuation changes. Countries may adopt other measures, such as controls on imports or exports of goods, technology, or data, that could adversely impact the Company' s operations and supply chain and limit the Company' s ability to offer our products and services as designed. These measures could 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. Any of these events could increase the cost of our products and services, or otherwise have a materially adverse impact on our or our suppliers' businesses and results of operations. **We have entered into agreements related to the manufacture of portions of our LUNA System in development. If we are unable to manufacture the LUNA System under the terms of these agreements, our business could be negatively impacted.** Fluctuations in foreign currency exchange rates may adversely affect our financial results. We conduct operations in several different countries, including the United States and throughout Europe, and portions of our revenues, expenses, assets and liabilities are denominated in U. S. dollars, Euros, and other currencies. Since our consolidated financial statements are presented in U. S. dollars, we must translate revenues, income and expenses, as well as assets and liabilities, into U. S. dollars at exchange rates in effect during or at the end of each reporting period. We have not historically hedged our exposure to foreign currency fluctuations. Accordingly, increases or decreases in the value of the U. S. dollar against the Euro and other currencies could materially affect our net operating revenues, operating income and the value of balance sheet items denominated in foreign currencies. ~~25Our~~ -- **Our** global operations expose us to additional risks and challenges associated with conducting business internationally. The international nature of our business, particularly in Europe, Israel, Asia **, CIS** and the Russian Federation, may expose us to risks inherent in conducting foreign operations. These risks include: challenges associated with managing geographically diverse operations, which require an effective organizational structure and appropriate business processes, procedures and controls; the high cost of doing business in foreign jurisdictions, including compliance with international and U. S. laws and regulations that apply to our international operations; currency exchange and interest rate fluctuations and the resulting effect on our revenue and expenses, and the cost and risk of entering into hedging transactions, if we chose to do so in the future; changes in a specific country' s or region' s political or economic environment; trade protection measures, import or export licensing requirements or other restrictive actions by U. S. or non- U. S. governments; potentially adverse tax consequences; complexities and difficulties in obtaining protection and enforcing our intellectual property;

compliance with additional regulations and government authorities in a highly regulated business; difficulties associated with staffing and managing foreign operations, including differing labor relations; and general economic and political conditions outside of the U. S. ~~The risks that we face in~~ **Significant disruptions of our information technology systems** ~~our~~ **or data security incidents** ~~international operations may continue to intensify as we further develop and expand our international operations. We expect our gross margins to vary over time, and changes in our gross margins~~ could **harm our reputation, cause us to modify our business practices, and otherwise** adversely affect our **business and subject us to liability. We are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process, and transmit sensitive corporate, personal, and other information, including intellectual property, proprietary business information, customer data including PII, and other confidential information. Our obligations under applicable laws, regulations, contracts, industry standards, self- certifications, and other documentation may include maintaining the confidentiality, integrity, and availability of personal information in our possession or control, maintaining reasonable and appropriate security safeguards as part of an information security program. These obligations create potential legal liability to regulators, our business partners, our customers, and other relevant stakeholders, and also impact the attractiveness of our products and services to existing and potential customers. Our systems are subject to cyber- attacks, viruses, worms, malicious software programs, outages, equipment malfunction or constraints, software deficiencies, human error, hacking and other malicious intrusions, which may materially disrupt our business and compromise our data. Cyber- attacks are expected to accelerate on a global basis in both frequency and magnitude as threat actors are becoming increasingly sophisticated in using techniques and tools (including artificial intelligence) that circumvent controls, evade detection and even remove forensic evidence of the infiltration. There can be no assurance that the systems we have designed to prevent or limit the effects of cyber incidents or attacks will be sufficient to prevent or detect material consequences arising from such incidents or attacks, or avoid a material adverse impact on our systems after such incidents or attacks do occur. Even if we successfully defend our own digital technologies, we also rely on providers of third- party products, services, and networks, with whom we may share data and services, and who may be unable to effectively defend their digital technologies and services against attack. Unauthorized access to or modification of, or actions disabling our ability to obtain authorized access to, our customers' data, other external data, personal data, or our own data, as a result of a cyber incident, attack or exploitation of a security vulnerability, or loss of control of our clients' operations could result in significant damage to our reputation or disruption of the services we provide to our customers or of our customers' businesses. In addition, allegations, reports, or concerns regarding vulnerabilities affecting our digital products or services could damage our reputation. We may not be able to anticipate and prevent such disruptions or intrusions, and we may not be able to mitigate them when and if they occur. Any failure, breach or unauthorized access to our or third- party systems could result in the loss of confidential, sensitive or proprietary information, interruptions in service or production or otherwise encumber our ability to conduct business operations and could result in potential reductions in revenue and profits, damage to its reputation or liability. Furthermore, we may incur significant costs in responding to any such disruption or intrusion and remedying our systems. In such event we may also be subject to litigation and other potential liability, which could materially impact our business and** financial condition **. Further, as regulatory focus on privacy and data security issues continues to increase and worldwide laws and regulations concerning the protection of information become more complex, the potential risks and costs of compliance to the company' s business will intensify. Although we have implemented remote working protocols for some employees and offer work- issued devices to employees, the actions of our employees while working remotely may have a greater effect on the security of our systems and the data we process, including by increasing the risk of compromise to our systems, intellectual property, or data arising from employees' combined personal and private use of devices, accessing our systems or data using wireless networks that we do not control, or the ability to transmit or store company- controlled data outside of our secured network. We maintain insurance policies to cover certain losses relating to our information technology systems. However, there may be exceptions to our insurance coverage such that our insurance policies may not cover some or all aspects of a security incident. Even where an incident is covered by our insurance, the insurance limits may not cover the costs of complete remediation and redress that we may be faced with in the wake of a security incident. The successful assertion of one or more large claims against us that exceeds our available insurance coverage,** or results ~~of operations. We began selling the Senhance System~~ in ~~2015. Our gross margins~~ **changes to our insurance policies (including premium increases or the imposition of large deductible or co- insurance requirements), could** have ~~fluctuated from period to period, and~~ **an adverse effect on our business. In addition,** we ~~expect~~ **cannot be sure** that ~~they~~ **our existing insurance coverage and coverage for errors and omissions** will continue to ~~fluctuate in the~~ **be available on acceptable terms or that our insurers will not deny coverage as to any** future **claim. In addition, any actual or perceived failure by us, our vendors, or our business partners to comply with our privacy, confidentiality, or data security- related legal or other obligations to customers or other third parties, or any further security incidents or other unauthorized access events that result in the unauthorized access, release, or transfer of sensitive information (which could include personal data), may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including current and potential partners, to lose trust in us (including existing or potential customers' perceiving our products or services as less desirable), or we could be subject to claims by third parties that we have breached our privacy- or confidentiality- related obligations, which could materially and adversely affect our business and prospects. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages. The conflict in Israel and Gaza is likely to have a material adverse impact on us and our employees. We have an office and valued employees who live and**

work in Israel. The current conflict in Israel could have a material adverse impact on our business and operations . Our ~~gross margins~~ **digital surgery software development efforts are centered in our Israeli subsidiary, and the conflict could cause unexpected delays in our development efforts. Some of our employees** have been **called** ~~and may continue~~ to **active military duty. In addition, a third- party manufacturer of our ISU located in Israel could** be ~~adversely affected by numerous~~ **negatively impacted affecting our ability to meet our supply obligations, and export of such ISUs, and other supply management activities and materials due to transport restrictions. If the conflict is prolonged or significantly worsens, these** factors **could have a** ~~, including: service costs, changes in customer, geographic or product mix; the number of Senhance Systems sold vs. placed, our ability to maintain or reduce production costs, changes in production volume driven by demand for our products, changes in~~ material **adverse** ~~, labor or other manufacturing- related costs, including increases in costs relating to global supply shortages and inflation, and the~~ impact ~~of foreign exchange rate fluctuations for foreign- currency denominated costs, fluctuations in foreign currency exchange rates and changes to U. S. and foreign trade policies, including the enactment of tariffs~~ on ~~goods imported into the U. S., inventory obsolescence and 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, results of~~ operations **and employees** ~~or cash flows may be materially adversely affected~~ . We face risks arising from sole suppliers of components and our ability to meet delivery schedules for sales of our products. The Senhance System is manufactured for us under contract by a third- party manufacturer. We or our manufacturer acquire raw materials and components of the Senhance System from vendors, some of which are sole suppliers. Although we believe that we have the manufacturing capacity and inventory reserves to meet our anticipated Senhance System sales for the foreseeable future, we are currently taking steps to develop redundant manufacturing and supply alternatives. We cannot assure you that we will be successful in developing these redundant supply and manufacturing capabilities. If we are not successful, our business operations could suffer. Our products require precise, high- quality manufacturing. We and our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and non- U. S. regulatory authorities to ensure strict compliance with the quality systems regulations, current " good manufacturing practices " and other applicable government regulations and corresponding standards. If we or our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. ~~Global supply shortages may prevent or restrict our ability to purchase adequate supplies of materials, parts and components at acceptable prices, which could result in delivery delays for our products or increases in our manufacturing costs. A disruption or termination in the supply of components could 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, results of operations, or cash flows. 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. Any such supply shortage could adversely impact our business, financial condition, results of operations, or cash flows. Labor shortages may disrupt our operations and result in delays in the manufacture and delivery of our products. Increased labor shortages globally, including staff burnout and attrition, could also impact our ability to hire and retain personnel critical to our manufacturing, logistics, and commercial operations. We are also highly dependent on the principal members of our management and scientific staff. Attracting and retaining qualified personnel is critical to our success, and competition for them has become more intense. The loss of critical members of our team, or our inability to attract and retain qualified personnel, could significantly harm our operations, business, and ability to compete. In addition, hospitals are also experiencing staffing shortages and supply chain issues that could impact their ability to provide patient care. 26The~~ inflationary environment could materially adversely impact our business and results of operations. Changes in economic conditions and supply chain constraints and steps taken by governments and central banks ~~, particularly in response to the COVID- 19 pandemic as well as other stimulus and spending programs,~~ could lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. An inflationary environment could have a negative impact on our expenses, increase our labor costs and reduce our available cash flow. Because our design, development and manufacturing capabilities are limited, we rely on third parties to design, develop, manufacture or supply some of our products. An inability to find additional or alternate sources for these services and products could materially and adversely affect our financial condition and results of operations. We have used third- party design and development sources to assist in the design and development of our medical device products. In the future, we may choose to use additional third- party sources for the design and development of our products. If these design and development partners are unable to provide their services in the timeframe or to the performance level that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the manner that we require. ~~Natural disasters and the effects of climate change could disrupt our business and harm our financial condition. The effects of climate change, weather or other events could adversely impact our supply chain, including our ability to manufacture our products, source materials or components or services from suppliers (including sole- source suppliers) that are needed for such manufacturing (including sterilization), or provide products to our customers, including events that impact key distributors. Natural disasters, including the impacts of climate change, hurricanes, tornadoes, windstorms, fires, earthquakes and floods and other extreme weather events, global health pandemics, war, terrorism, labor disruptions and international conflicts that could cause significant economic~~

disruption and political and social instability, could result in decreased demand for our products, or adversely affect our manufacturing and distribution capabilities or cause interruptions in our supply chain. Our operations, and the activities of our customers, vendors or distributors, could be disrupted by climate change. The physical changes caused by climate change may prompt changes in regulations or consumer preferences which in turn could have negative consequences for our and our customers' businesses. Potential physical risks from climate change may include altered distribution and intensity of rainfall, prolonged droughts or flooding, increased frequency of wildfires and other natural disasters, rising sea levels, and a rising heat index, any of which could cause negative impacts to our and our customers' businesses. If such events affect our customers' businesses, they may purchase fewer of our products, and our revenues may be negatively impacted. There has been a broad range of proposed and promulgated state, national and international regulations aimed at reducing the effects of climate change. Such regulations could result in additional costs to maintain compliance and additional income or other taxes. Climate change regulations continue to evolve, and it is not possible to accurately estimate potential future compliance costs. Our stock price has been volatile and may experience additional volatility and fluctuation in the future. The market price of our common stock has been, and may continue to be, volatile, and the market price of our common stock could decrease and could cause you to lose some or all of your investment in our common stock. During the two- year period ended December 31, 2022 **2023** , the market price of our common stock fluctuated from a high of $ 6 **1** . 95 **19** per share to a low of $ 0. 28 **20** per share. The market price of our common stock may continue to fluctuate significantly **. In addition** in response to numerous factors , some of which are beyond **a prolonged low stock price may subject us to delisting** our **or** control **require us to take action** , such as **a reverse** • the announcement of favorable or unfavorable news regarding us, including our product development efforts and regulatory clearance activities; • the achievement of lease placements or commercial sales of our products; • the announcement of new products or product enhancements or collaborations by us or our competitors; • variations in our and our competitors' results of operations; • future issuances of common stock **split, to maintain** or **our listing** other securities; • the addition or departure of key personnel; • announcements by us or our competitors of acquisitions, investments or strategic alliances; and • general market conditions and other factors, including factors unrelated to our operating performance . 27We **We** are currently a smaller reporting company, which may limit our ability to raise sufficient capital to advance our LUNA System and Performance- Guided Surgery development efforts. Our stock price was below $ 1. 00 per share during much **all** of 2022 **2023** . If our stock price continues to remain under a $ 1. 00 per share for an extended period, **that** we will be subject to the SEC' s " baby shelf " rules, which may limit the amount of capital we can raise over a twelve month period under a Form S- 3 registration statement. Such rules may make **makes fundraising** our capital financing transactions more difficult **and impacts** or **our** expensive **ability to attract long- term investors** . Our stockholders have experienced dilution of their percentage ownership of our stock and may experience additional dilution in the future. We have raised significant capital through the issuance of our common stock and warrants and anticipate that we may need to raise substantial additional capital in order to continue our operations and achieve our business objectives. We cannot assure you that we will be able to sell shares or other securities in any offering at a price per share that is equal to or greater than the price per share paid by investors in previous offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in previous offerings. The future issuance of the Company' s equity securities will further dilute the ownership of our outstanding common stock. The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause stockholders to lose some or all of their investment in our common stock. We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock. At the present time, we intend to use available funds to finance our operations. Accordingly, while payments of dividends is within the discretion of our board of directors, no cash dividends on our common stock have been declared or paid by us, and we have no intention of paying any such dividends in the foreseeable future. Any return to investors is expected to come, if at all, only from potential increases in the price of our common stock. Risks Related to Protection of our Intellectual Property Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. **If** In addition, to the extent that a third- party **has proprietary rights covering** develops new technology that covers our products, we may be required **require** to obtain licenses to that technology , which licenses may not be available or may not be available on commercially reasonable terms, **if or** at all. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third- party patent or circumvent the third- party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. If we become involved in patent litigation or other proceedings related to **proprietary** a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts, any of which could materially adversely affect our liquidity, business prospects and results of operations. Third parties may sue us for infringing their patent **patents** rights . Likewise, we may need to resort to litigation to enforce a **our** patent **patents** issued or licensed to us or to determine the scope and validity of **patents** proprietary rights of others. In addition, a third- party may claim that we have improperly obtained or used its confidential or proprietary information. Furthermore, in connection with our third- party license agreements, we generally have agreed to indemnify the licensor for costs incurred in connection with litigation relating to intellectual property rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor,

could be substantial, and the litigation would divert our management' s efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us because they have substantially greater resources. Uncertainties resulting from ~~the initiation and continuation of~~ any litigation could limit our ability to continue our operations. If any parties successfully claim that our **activities** ~~creation or use of proprietary technologies infringes~~ -- **infringe** ~~upon~~ their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed ~~on such parties' patent rights~~. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non- exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to ~~effectively~~ market some of our ~~technology and~~ products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. ~~28For~~ -- **For** our Senhance System, we rely on our license from the European Union, and any loss of our rights under such license agreement, or failure to properly prosecute, maintain or enforce the patent applications underlying such license agreement, could materially adversely affect our business prospects for the Senhance System. Some of the patents and patent applications in our patent portfolio related to the Senhance System are licensed to Asensus Surgical Italia S. r. l. under a license agreement with the European Union. **We** ~~Presently, we~~ rely on such licensed technology for our Senhance System ~~products and~~ **. We** may license additional technology from ~~the European Union or other~~ third parties in the future. The EU ~~license~~ agreement gives us rights for the commercial exploitation of the licensed patents, ~~patent applications and know- how,~~ subject to certain provisions of the ~~license~~ agreement. Failure to comply with these provisions could result in the loss of our rights under the EU license agreement. Our inability to rely on these patents ~~and patent applications which are the basis of certain aspects of our Senhance System technology~~ would have an adverse effect on our business. Further, our success will depend in part on the ability of us, the **EU** ~~European Union~~ and other third- party licensors to obtain, maintain and enforce **the** ~~patent protection for our~~ licensed **patents** ~~intellectual property~~ and, in particular, those patents to which **hold** ~~we have secured~~ exclusive rights. We, the **EU** ~~European Union~~ or other third- party licensors may not successfully prosecute the patent applications which are licensed to us, may fail to maintain ~~these~~ -- **the** patents, and may determine not to pursue litigation against other companies that are infringing ~~these~~ -- **the** patents, or may pursue such litigation less aggressively than necessary to obtain an acceptable outcome from any such litigation. Without protection for the intellectual property we have licensed, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and results of operations. If we or our licensors are unable to protect the confidentiality of our proprietary information and know- how, the value of our technology and products could be adversely affected. In addition to patent protection, we ~~also~~ rely on other proprietary rights, including protection of trade secrets, know- how ~~and confidential~~ and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual' s relationship with us be kept confidential ~~and not disclosed to third parties~~. Our agreements with employees also generally provide ~~and will generally provide~~ that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection ~~, particularly for our trade secrets or other confidential information~~. **If** ~~To the extent that~~ our employees, consultants or contractors use technology or know- how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations ~~.~~ If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed. Our success depends, in part, on our ability to protect proprietary ~~methods and~~ technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold ~~proprietary~~ rights to some patents required for us to commercialize our proposed products. ~~Because certain U. S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third~~ **Third** parties may have filed patent applications for technology covered by our ~~pending~~ patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we ~~or our third- party collaborators~~ may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third- party patent or otherwise circumvent the third- party patent. Our strategy depends on our ability to promptly identify and seek patent protection for our discoveries. In addition, we may rely on third- party collaborators to file patent applications **for inventions** ~~relating to proprietary technology that~~ we develop jointly during certain collaborations. The process of obtaining ~~patent~~ **patents** ~~protection~~ is expensive and time- consuming. If our ~~present or future~~ collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business will be adversely affected. Despite our efforts and the efforts of our collaborators to protect our proprietary rights, unauthorized parties may be able to develop and use information that we regard as proprietary. ~~29The~~ -- **The** issuance of a patent ~~provides a presumption, but~~ does not guarantee that it is valid. Any patents we have obtained, or obtain in the future, may be challenged or potentially circumvented. Moreover, the **US** ~~United States~~ Patent and Trademark Office, or the USPTO, may commence

interference proceedings involving our patents or patent applications. Any ~~such~~ challenge to our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, future court decisions may introduce uncertainty in the enforceability or scope of any patent ~~, including those owned by medical device companies~~. Our pending patent applications may not result in issued patents. ~~The~~ **A business' s** patent position ~~of medical device companies~~, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our owned or licensed patents in the **US** ~~United States~~ or in foreign countries cannot be predicted with certainty, and, as a result, ~~any~~ **such** patents ~~that we own or license~~ may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties. We cannot assure you that any patents that ~~will~~ issue ~~, that may issue~~ or ~~that may~~ be licensed to us will be enforceable or valid or will not expire prior to the commercialization of our products, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our future products. Certain software being developed for the LUNA System and the ISU may include third- party open source software. Any failure to comply with the terms of one or more open source software licenses could adversely affect our business, subject us to litigation, or create potential liability. Certain software being developed for the LUNA System and for the ISU may include third- party open source software and we expect to continue to incorporate open source software in the future. The use of open source software involves a number of risks, many of which cannot be eliminated and could negatively affect our business. For example, we cannot ensure that we have effectively monitored our use of open source software or that we are in compliance with the terms of the applicable open source licenses or our current policies and procedures. There have been claims against companies that use open source software asserting that the use of such open source software infringes the claimants' intellectual property rights. As a result, we could be subject to suits by third parties claiming infringement on such third parties' intellectual property rights. Litigation could be costly for us to defend, have a negative effect on our business, financial condition and results of operations, or require us to devote additional research and development resources to modify our computational drug discovery platform. ~~Use of open source software may entail greater risks than use of third- party commercial software, as open source licensors generally do not provide warranties, controls on the origin of the software or other contractual protections regarding infringement claims or the quality of the code, including with respect to security vulnerabilities. In addition, certain open source licenses require that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. The terms of various open source licenses have not been interpreted by courts in the relevant jurisdictions, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market our solutions. By the terms of certain open source licenses, if portions of our proprietary software are determined to be subject to an open source license or if we combine our proprietary software with open source software in a certain manner, we could be required to release the source code of our proprietary software and to make our proprietary software available under open source licenses, each of which could reduce or eliminate the effectiveness of our computational discovery efforts. We may also face claims alleging noncompliance with open source license terms or misappropriation or other violation of open source technology. Any of these events could create liability for us and damage our reputation, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.~~ Risks Related to Regulation of our Business **For our existing product** ~~Even if we obtain regulatory~~ clearances ~~or ,~~ approvals **, or certifications and** for our **future** products, the terms thereof and ongoing regulation of our products may limit how we manufacture and market our products, which could materially impair our ability to generate anticipated revenues. **If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.** Once regulatory clearance ~~or ,~~ approval **or certification** has been ~~granted~~ **obtained** , the cleared ~~or ,~~ approved **or certified** product and its manufacturer are subject to ~~continual review~~ **ongoing regulatory requirements** . Any cleared ~~or ,~~ approved **or certified** product may be promoted only for its intended uses. In addition, if the FDA ~~or ,~~ other non- U. S. regulatory authorities **, or our Notified Body** clear ~~or ,~~ approve **, or certify** any of our products, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory oversight. We and any outsourced manufacturers of our products are also required to comply with the FDA' s QSR, or similar requirements of non- U. S. regulatory authorities which includes requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation as well as other quality system requirements and regulations from non- U. S. regulatory authorities. Further, all manufacturing facilities are subject to routine regulatory inspection. ~~30If~~ **Regulatory authorities, such as the FDA in the U. S., and notified bodies enforce regulatory requirements through periodic inspections, among other activities. If** we fail to comply with the regulatory requirements of the FDA, either before or after clearance or approval, or other non- U. S. regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including: restrictions on our products, manufacturers or manufacturing process; adverse inspectional observations (Form 483), Warning Letters, **Untitled Letters,** letters incorporating inspectional observations, or consent decrees; civil or criminal penalties or fines; injunctions; product seizures, detentions or import bans; voluntary or mandatory product recalls and publicity requirements; suspension **limitation** or withdrawal of

regulatory clearances ~~or ,~~ approvals **, or certifications** ; total or partial suspension of production; imposition of restrictions on operations, including costly new manufacturing requirements; refusal to clear or approve pending applications or premarket notifications; and import and export restrictions. Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. ~~Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, the FDA and other non- U. S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory clearance or approval of our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future products and we may not achieve or sustain profitability. Once our products are cleared or approved, modifications to our products may require new 510 (k) clearances, de novo clearance, premarket approvals or new or amended CE Certificates of Conformity, and may require us to cease marketing or recall the modified products until clearances, approvals or the relevant CE Certificates of Conformity are obtained. Any modification to a 510 (k)- cleared or CE marked device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use requires a new 510 (k) clearance or, possibly, PMA approval or de novo authorization or review by the Notified Body for CE marked devices. The FDA or Notified Body requires every manufacturer to make this determination in the first instance, but the FDA / Notified Body may review such determinations. The FDA / Notified Body may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA / Notified Body disagrees with our determinations for any future changes, or prior changes to previously marketed products, we may be required to cease marketing or to recall the modified products until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, the FDA' s review of the 510 (k) program may make it more difficult for us to make modifications to our products, either by imposing more strict requirements on when a new 510 (k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. In October 2017, the FDA issued guidance documents addressing when to submit a new 510 (k) notice for modifications to cleared products and the criteria for evaluating substantial equivalence. The interpretation of the guidance documents by the FDA staff could lead to instances where the FDA disagrees with the Company' s decision regarding a change, and could result in Warning Letters and other enforcement actions.~~ Our future success depends on our ability to develop, receive regulatory clearance ~~or ,~~ approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510 (k) clearance **, de- novo authorization** or PMA approval **, or that a Notified Body will issue the relevant CE Certificates** of **Conformity, of / to** our future products on a timely basis, if at all, and failure to obtain necessary clearances ~~or ,~~ approvals **or certifications** for our future products would adversely affect our ability to grow our business. When a 510 (k) notice, de novo request, or PMA is submitted for a new product or for a change to an existing product, there is no guarantee that it will receive FDA authorization. Failure to receive clearance or approval for our new products or indications for use would have an adverse effect on our ability to expand our business. ~~For example, the FDA review process is ongoing for our 510 (k) notice to expand the Senhance System indications to pediatric use.~~ If we do not receive clearance for ~~this~~ **any device enhancements, modifications or** expanded indication, we will not be able to market the **modified** device ~~for pediatric procedures~~ in the U. S. **or other foreign countries** until such clearance **, approval, authorization or certification** is obtained. ~~31Our~~ -- **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 **or our distributor** 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 timing to obtain clearances or certifications in those 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. The time required to obtain marketing authorization in other countries might differ from that required to obtain FDA authorization. If we **or our distributor** 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. Regulatory authorization of a product in one country does not ensure regulatory authorization in another, but a failure or delay in obtaining marketing authorization in one country may negatively impact the regulatory process in others. One of the most significant moving targets related to the regulatory landscape is in the EU; more specifically, the medical devices regulation has recently evolved. Regulation (EU) 2017 / 745 on medical devices **(the MDR)** became applicable in the European Union on May 26, 2021. The MDR, which replaced the MDD in May 2021 **(subject to certain** ~~after a four- year transition~~ **transitional provisions)** ~~period, which has now been extended to a seven- year transition period for some class IIb and class IIa,~~ imposes significant additional premarket and post- market certification requirements on medical devices marketed in the EU. European Economic Area (EEA) Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare providers harming our business, operating results and financial condition. If we are unable to obtain timely ~~, updated post- market~~ certifications for our products under the MDR, or experience difficulty scheduling with a Notified Body, our business prospects in the EU could be materially adversely affected, which could have a material adverse effect on our financial results. **Our** ~~Even after clearance or approval for our~~ products ~~is obtained,~~ **may cause or contribute to adverse events or be subject to failures or malfunctions that** we are ~~subject~~ **required** to **report to** ~~extensive post- market regulation by~~ the FDA ~~and other regulators. Our failure to~~

~~meet strict regulatory requirements could require us to pay fines, incur other costs or even close our~~ **or comparable foreign** ~~facilities. Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post- market studies. These studies can be very expensive and time- consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States. The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and efficacy of our products. We are also required to comply with the FDA' s QSR, which covers the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, installation and servicing of our marketed products. The FDA enforces the QSR through periodic announced and unannounced inspections of manufacturing facilities. In addition, in the future,~~ regulatory authorities and ~~/ or customers may require specific packaging of sterile products, which could increase our costs and the price of our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. If one of our products, or a malfunction of one of our products, causes or contributes to a death or a serious injury, we will be subject to medical device reporting regulations, which~~ can result in voluntary corrective actions or agency enforcement actions. Under the FDA' s regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death, serious health threat or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated **adverse events or** product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost- effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition. ~~We are also required to follow detailed recordkeeping requirements for all firm- initiated medical device corrections and removals, and to report such corrective and removal actions to the FDA if they are carried out in response to a risk to health and have not otherwise been reported under the regulations.~~ All manufacturers bringing medical devices to market in the EEA are legally bound to report any incident that **directly or indirectly** led ~~or ,~~ might have led **or might lead** to the death or serious deterioration in the state of health of a patient, user or other person **, or to a serious public health threat** , and which the manufacturer' s device is suspected to be a contributory cause, to the competent authority in whose jurisdiction the incident occurred. In such case, the manufacturer must file an initial report with the relevant competent authority, which would be followed by further evaluation or investigation of the incident and a final report indicating whether further action is required. Any ~~adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events involving our products have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any~~ corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. ~~32A~~ **A** recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. The FDA and similar foreign governmental authorities such as the competent authorities of the EEA countries have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. ~~A government- mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.~~ Any future recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. Our employees, consultants, third-party vendors and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee, consultant, third- party vendor or collaborator fraud or other misconduct. Misconduct by our employees, consultants, third- party vendors or collaborators could include, among other things, intentional failures to comply with FDA, EU or other regulations, provide accurate information to the FDA or other regulators, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us ~~. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. It is not always possible to identify and deter such misconduct, 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 be in compliance with such laws or regulations~~ . 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 material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us. **Clinical trials may be necessary to support our future product submissions to**

the FDA or Notified Bodies and such trials are lengthy, regulatory nuanced, interactive and involve working with third parties. These and other factors may affect our ability to complete clinical trials and may lead to delays or failures that would affect our business and financial prospects. Initiating and completing clinical trials necessary to support any future products, including those that may require PMAs, and additional safety and efficacy data beyond that typically required for a 510 (k) clearance, for our possible future product candidates, will be time- consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products and product candidates conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical testing in addition to those we have planned. U. S. legislative, FDA regulatory reforms or global regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained. Legislative changes could significantly alter the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products. In addition, FDA regulations and guidance could be revised or reinterpreted by the FDA in ways that could significantly affect our business and our products. ~~Any~~ **For example, the FDA just finalized a rule to replace the QSR by adopting ISO 13485. Companies are required to come into compliance with this new rule by February 2026. This, and any** new regulations or revisions, or reinterpretations of existing regulations, may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations will be changed, and what the impact of such changes, if any, may be. We anticipate that future regulatory requirements may focus on artificial intelligence or clinical decision support products, such as our ISU, which may subject our products to additional regulations. Disruptions at the FDA and other government agencies or ~~notified~~ **Notified** ~~bodies~~ **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. The delivery of healthcare by hospitals, health systems, and physicians depends on a number of government agencies and services. Further prolonged government shutdowns or restrictions 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 review and clearance, approval, or certification of new products can be affected by a variety of factors globally, including government budget and funding levels, global health concerns, 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 unpredictable and ever- changing political processes. Disruptions at the FDA and other agencies or ~~notified~~ **Notified** ~~bodies~~ **Bodies** for any of these or other reasons 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, results of operations, or cash flows. 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. ~~33We~~ **We** may be subject, directly or indirectly, to federal and state anti- kickback, fraud and abuse, false claims, privacy and security and physician payment transparency laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Our business activities are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. ~~Such~~ **Restrictions under applicable federal and state healthcare** laws **and regulations that may affect our operations (** ~~include~~ **including our marketing** , **promotion** ~~without limitation~~ , **educational programs** ~~state and federal anti- kickback~~ , **pricing** ~~fraud and abuse~~ , ~~false claims, privacy~~ and ~~security~~ **relationships with healthcare providers or other entities, among other things)** and ~~physician payment transparency laws further~~ **expose us to areas of risk are** described ~~under~~ **in the** " Business **- Health Care Regulation** " ~~above~~ **section of this Annual Report** . **Additionally,** ~~Some~~ **some state** ~~such laws, including~~ privacy laws, may include private rights of action and can lead to class action litigation **. Other laws, such as the FCA, can be enforced through qui tam actions brought by individuals on behalf of the government. Efforts to ensure that our business arrangements with third parties are compliant with applicable healthcare laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations** . If our operations are found to be in violation of any of such laws that apply to us, we may be subject to **significant** penalties, including, without limitation, civil ~~and~~ **,** criminal **, and administrative** penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs **such as Medicare and Medicaid,** and imprisonment, any of which could adversely affect

our ability to operate our business and our financial results. **Failure of our customers to obtain adequate reimbursement for procedures using our current or new products could limit our ability to market those products and decrease our ability to generate revenue. Our products are sold or leased to facilities, such as hospitals, and are not for use in the home such that they are not durable medical equipment. Devices such as ours used in surgical procedures are normally not paid separately by payers, but are reimbursed by third- party payors as part of the payment made for the performed surgical procedure when performed on an outpatient basis, or as part of the payment made for the inpatient stay when the patient undergoing the procedure is an inpatient of a hospital. As a result, these types of devices are subject to significant price competition that can place a small manufacturer at a competitive disadvantage as facilities attempt to negotiate lower prices for products such as the ones we develop and sell. The pricing of products and procedures have come under increasing scrutiny as part of a global trend toward healthcare cost containment. Resulting changes in healthcare law and policy, including changes to Medicare, may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition. The United States is considering, or has already enacted or implemented, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably, described in a streamlined manner below and are described in the " Business- Health Care Regulation " section of this Annual Report Form 10- K. We expect to experience pricing pressures in connection with the sale of any products that we develop, and the procedures in which they are used, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative and regulatory measures. The U. S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government- paid health care costs, including price controls and restrictions on reimbursement. If healthcare policies or reforms intended to curb healthcare costs are adopted, the prices that we charge for our products may be limited, our commercial opportunity may be limited and / or our revenues from sales of our product and any future products, if approved, may be negatively impacted.** We are subject to an evolving set of complex laws and regulations relating to privacy, data protection and information collection matters. There are numerous state, federal, and foreign laws, regulations, decisions, and directives regarding privacy rights and the ~~collection, storage, transmission, use,~~ processing ~~, disclosure, and protection~~ of ~~different types of personal data and personal~~ information **relating to identified or identifiable persons (" Personal Information ")** and other **categories of** ~~customer or other~~ data, the scope of which is continually evolving and subject to differing interpretations. We also must comply with the policies, procedures and business requirements of our customers relating to data privacy and security, which can vary based upon the customer, the customer' s industry or location, and the product the customer selects, and which may be more restrictive than the privacy and security measures required by law or regulation. Around the world, the privacy and data protection legal landscape is rapidly changing, which may require us to adjust aspects of our operations or expend significant time and resources to come into compliance with new laws or regulatory obligations. In particular, the European ~~Union~~ **Economic Area (" EEA "), the United Kingdom** and **Switzerland** ~~many countries in Europe~~ have stringent privacy laws and regulations, which may impact our ability to profitably operate in certain European countries or to offer products that meet the needs of customers subject to **EU** ~~European Union~~ privacy laws and regulations. For example, the **General Data Protection Regulation (the "** GDPR **")** provides that EEA Member States may make their own further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to use and share ~~personal~~ **Personal** ~~data~~ **Information** or could cause our costs to increase and harm our business and financial condition. ~~Failure to comply~~ **Non-compliance** with the ~~requirements of the~~ GDPR and the applicable ~~national data protection~~ **EEA Member State** laws ~~of the EEA member states~~ may result in fines of up to 4 % of the total worldwide annual turnover of the preceding financial year and other administrative penalties **, as well as adverse publicity** . ~~Compliance~~ **It also confers the right for data subjects to lodge complaints** with **supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of** the ~~new data protection rules imposed by~~ GDPR ~~may be onerous and adversely affect our business, financial condition, and results of operations~~ . Global laws **such as the GDPR** are increasingly restricting and regulating the cross- border transfer of ~~personal~~ **Personal** ~~data~~ **Information** , which may require us to ~~undertake~~ **implement** additional ~~obligations in order~~ **and, potentially, costly safeguards** to receive ~~personal~~ **Personal** ~~data~~ **Information** from overseas customers or transfer such data, including to our vendors. **I** For example, ~~the GDPR restricts the ability of companies to transfer personal data from the EEA to the United States and other countries~~ , ~~which may adversely affect our ability to transfer or receive personal data or otherwise may cause us to incur significant costs to undertake data transfer impact assessments and implement lawful data transfer mechanisms. Some available lawful transfer mechanisms are under scrutiny and~~ in ~~flux~~ **June 2021** , ~~such as~~ the European Commission ~~' s~~ **adopted a new set of** Standard Contractual Clauses **(" SCCs ")** , **aimed at enabling lawful transfers** ~~or the Model Clauses and the recently invalidated Privacy Shield Frameworks. The Model Clauses may continue to be subject to scrutiny as a result~~ of **Personal Information to non- adequate countries outside** the **EEA, and on** ~~European Court of Justice' s judgement in~~ July **10,** ~~2020~~ **2023** ~~, though they~~ **the** ~~remain the most common authorized procedure to transfer personal data out of the EU. The~~ European Commission **adopted its adequacy decision for** ~~and U. S. regulators are expected to revive a version of~~ the EU- US **Data** Privacy ~~Shield~~ Framework, ~~which may ease the burden of~~ **meaning that personal data can now flow freely from** ~~these~~ ~~-~~ **the** ~~cross- border transfers~~ **EEA to US companies that participate in the Data Privacy Framework** . ~~Still, any approved~~ **A lack of valid** transfer ~~framework likely will face scrutiny and lawsuits from privacy advocacy groups, which may result in the invalidation of a transfer mechanism~~ **mechanisms** ~~on which we or~~ **for Personal Information subject** ~~our customers rely, which may impede our ability~~ to **GDPR could increase exposure to enforcement** ~~transfer or receive data from the EEA. Our continued monitoring of and reactions~~ ~~-~~ **actions** ~~to these legal developments can~~ **as described above, and may** affect our ~~customer base,~~ business operations ~~,~~ and **require commercial** ~~costs~~ ~~-~~ **cost** ~~of doing business abroad. Other countries are implementing~~ **(including potentially limiting our ability to collaborate / work with certain third parties and /**

or requiring an increase in our data ~~localization requirements or restrictions or obstacles~~ **processing capabilities in the EU / U. K.). Further, the EEA / U. K., and Swiss data protection laws (including laws** on **data** ~~the cross- border~~ transfers ~~of personal data, such~~ as ~~requiring express consent~~ **set out above) may also be updated / revised** , ~~notification to local authorities~~ **accompanied by new guidance and / or judicial / regulatory interpretations** , **which could entail further impacts on** ~~or~~ **our** ~~assessments~~ **compliance efforts** and **increased cost** ~~contractual amendments similar to the GDPR requirements~~ . ~~34In~~ **In** addition to the laws specifically discussed, numerous other federal and state laws and regulations govern privacy and security, including state data breach notification laws, state health information and / or genetic privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act, new state consumer protection laws), many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space. The costs of compliance with, and other burdens imposed by, our customers' own requirements ~~and ,~~ the privacy and security laws and regulations ~~that are applicable to our customers' businesses may limit the use and adoption of our products and reduce overall demand. Non- compliance with our customers' specific requirements may lead to termination of contracts with these customers or liabilities to the customers; non- compliance with applicable laws and regulations may lead to significant fines~~ , **as well as** ~~penalties or liabilities. In addition to government activity, privacy advocacy groups and the technology and other industries are considering various new, additional or different~~ self- regulatory standards that ~~may place additional burdens on~~ **are applicable to us and** our ~~software~~ **customers' businesses may limit the use and adoption of our** products **, reduce overall demand and may incur substantial cost or require us to change our business practices** . ~~Complying~~ **Non- compliance with our customers' specific requirements may lead to termination of contracts** with these ~~varying requirements could cause us to incur substantial costs or require it to change our business practices in a manner adverse to our business. Any failure, or perceived failure, on our part to comply with any regulatory requirements or international privacy or consumer protection- related laws and regulations could result in proceedings or actions against it by governmental entities or others, subject it to significant penalties or fines and negative publicity and adversely affect us. Significant disruptions of our information technology systems or data security incidents could harm our reputation, cause us to modify our business practices, and otherwise adversely affect our business and subject us to liability. We are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process, and transmit sensitive corporate, personal, and other information, including intellectual property, proprietary business information, customer data, and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. Our obligations under applicable laws, regulations, contracts, industry standards, self- certifications, and other documentation may include maintaining the confidentiality, integrity, and availability of personal information in our possession or control, maintaining reasonable and appropriate security safeguards as part of an information security program. These obligations create potential legal liability to regulators, our business partners, our~~ customers ~~, and other relevant stakeholders, and also impact the attractiveness of our~~ - **or liabilities** ~~products and services~~ to **the** ~~existing and potential~~ customers. ~~We rely on sophisticated information technology systems to operate our business. Our systems are subject to cyber- attacks, viruses, worms, malicious software programs, outages, equipment malfunction or constraints, software deficiencies, human error, hacking and other malicious intrusions, which may materially disrupt our business and compromise our data. We may not be able to anticipate and prevent such disruptions or intrusions, and we may not be able to mitigate them when and if they occur. Any failure, breach or unauthorized access to our or third- party systems could result in the loss of confidential, sensitive or proprietary information, interruptions in service or production or otherwise our ability to conduct business operations and could result in potential reductions in revenue and profits, damage to its reputation or liability. Furthermore, we may incur significant costs in responding to any such disruption or intrusion and remedying our systems. In such event we may also be subject to litigation and other potential liability, which could materially impact our business and financial condition. Moreover, a breach or disruption of our information technology systems could damage our reputation. Further, as regulatory focus on privacy and data security issues continues to increase and worldwide laws and regulations concerning the protection of information become more complex, the potential risks and costs of compliance to the company' s business will intensify. Although we have implemented remote working protocols for some employees and offer work- issued devices to employees, the actions of our employees while working remotely may have a greater effect on the security of our systems and the data we process, including by increasing the risk of compromise to our systems, intellectual property, or data arising from employees' combined personal and private use of devices, accessing our systems or data using wireless networks that we do not control, or the ability to transmit or store company- controlled data outside of our secured network. These risks have been heightened by the dramatic increase in the numbers of our employees who have been and are continuing to work from home. We maintain insurance policies to cover certain losses relating to our information technology systems. However, there may be exceptions to our insurance coverage such that our insurance policies may not cover some or all aspects of a security incident. Insurance policies will also not protect against the reputational harms caused by a major security incident. Even where an incident is covered by our insurance, the insurance limits may not cover the costs of complete remediation and redress that we may be faced with in the wake of a security incident. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co- insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. 35In addition, any actual or perceived failure by us, our vendors, or our business partners to comply with our privacy, confidentiality, or data security- related legal or other obligations to customers or other third parties,~~

~~or any further security incidents or other unauthorized access events that result in the unauthorized access, release, or transfer of sensitive information (which could include personal data), may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including current and potential partners, to lose trust in us (including existing or potential customers' perceiving our products or services as less desirable), or we could be subject to claims by third parties that we have breached our privacy- or confidentiality- related obligations, which could materially and adversely affect our business and prospects. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages. If we fail to attract and retain key management and professional personnel, we may be unable to successfully commercialize or develop our products. We will need to effectively manage our operational, sales and marketing, development and other resources in order to successfully pursue our commercialization and research and development efforts for our existing and future products. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel. If we are not successful in retaining and recruiting highly qualified personnel, our business may be harmed as a result. We may become subject to potential product liability claims, and we may be required to pay damages that exceed our insurance coverage. Our business exposes us to potential product liability claims that are inherent in the design, testing, manufacture, sale and distribution of our products and each of our product candidates that we are seeking to introduce to the market. Surgical medical devices involve significant risks of serious complications, including bleeding, nerve injury, paralysis, infection, and even death. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or in our inability to secure coverage in the future on commercially reasonable terms, if at all. In addition, if our product liability insurance proves to be inadequate to pay a damages award, we may have to pay the excess of this award out of our cash reserves, which could significantly harm our financial condition. If longer- term patient results and experience indicate that our products or any component of a product causes tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. A product liability claim, even one without merit, could harm our reputation in the industry, lead to significant legal fees, and result in the diversion of management' s attention from managing our business.~~
~~ITEM 1. B. UNRESOLVED STAFF COMMENTS~~