

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

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The ~~Company~~ frameworks often define requirements for marketing authorizations which vary by country. Failure to obtain appropriate marketing authorization and to meet all local requirements, including specific quality and safety standards and new software and AI standards in any country in which we currently market our products, could cause commercial disruption and / or subject us to sanctions and fines. Delays in receipt of, or a failure to receive, such marketing authorizations, or the loss of any previously received authorizations, could have a material adverse effect on our business, financial condition and results of operations. With regards to premarket authorization in the United States, many of our products are classified as medical devices under the U. S. Food, Drug, and Cosmetic Act (“ FD & C Act ”). The FD & C Act requires these products, when sold in the United States, to be safe and effective for their intended use and to comply with medical device regulations defined by the FDA. The regulatory framework depends on a set of written processes for ensuring consistent quality called a Quality Management System (“ QMS ”) coupled with a product marketing authorization which depends on the risk classification of the product. This regulatory framework is comparable to the framework established in the European Union (“ EU ”). Within the EU, our products are subject to the requirements defined by the Medical Device Regulation EU 2017 / 745 which replaced the Medical Device Directive 93 / 42 / EEC with a final transition date of May 26, 2021. Similar market access regulations exist in Brazil, China, Japan and other countries. Our QMS is routinely audited by certification bodies as well as country regulators for compliance with applicable regulations. We believe we are in material compliance with all state, federal, and international regulatory requirements applicable to our products. We are also subject to various laws around the world that govern interactions with our customers as healthcare professionals or government officials. The laws govern different interactions and may include: prohibiting improper influence of or payments to healthcare professionals, other decision makers or purchasers of medical devices and government officials; setting out rules for when and how to engage healthcare professionals; marketing our products within the regulatory approval (e. g., on label) promotion, sale and marketing of our products and services; the importing and exporting of our products; the operation of our facilities and distribution of our products; and disclosure of payments to healthcare professionals and institutions. As we expand our operations footprint, countries to which we sell and invest in new business models, compliance with applicable laws becomes more complex and the general trend is toward increasingly stringent oversight and enforcement. Initiatives sponsored by government agencies, legislative bodies, and the private sector to limit the growth of healthcare expenses generally are ongoing in markets where we do business. It is not possible to predict at this time whether these trends will impact our business or the potential cost containment measures on our future business. Our customers are healthcare providers that may be reimbursed by state or federal funded programs such as Medicaid, a foreign national healthcare program, or private pay insurance, each of which may offer some degree of oversight. As a medical device manufacturer and seller, we are subject to transparency reporting laws (also known as sunshine laws) that in certain countries and U. S. states require us to report transfers of value to healthcare professionals that perform services or receive other items from us (e. g., meals, travel, branded promotional or educational items, or other benefits of value). Enforcement actions and associated efforts to respond or defend against enforcement actions can be expensive, and any resulting findings carry the risk of significant civil and criminal penalties. In addition, we must comply with numerous laws and regulations addressing privacy, data protection, data governance and cyber security. Many of these laws and regulations do or will soon regulate or restrict cross- border data transfers, such as in the United States, the EU, Switzerland, Brazil, China, Vietnam, Japan, Korea, Australia, New Zealand, the Kingdom of Saudi Arabia, Hong Kong and other countries. Further, in the United States, we may be required to comply with laws and regulations addressing the collection, use, security and processing of protected health information and other information relating to individuals, including the Health Insurance Portability and Accountability Act of 1996 (“ HIPAA ”) and its implementing rules. The HIPAA Standards for Privacy of Individually Identifiable Health Information (“ Privacy Standards ”) and the Security Standards for the Protection of Electronic Protected Health Information under HIPAA and the Health Information Technology for Economic and Clinical Health Act of 2009 (“ HITECH Act ”) (the “ Security Standards ”) are the subjects of final and proposed rule amendments, respectively, reflecting the rapidly evolving nature of these laws and regulations. Additionally, many U. S. states maintain laws and regulations addressing privacy, data protection, data governance and cybersecurity. Like many other companies, we must work to ensure our global privacy program framework incorporates applicable requirements of new and modified laws and regulations in relevant jurisdictions to support our efforts to ensure that our product innovations and our associated practices comply with these increasingly complex laws and regulations. Legislatures and regulators globally are proposing, and in certain cases have enacted, new laws or regulations regarding privacy, data protection, data governance and cybersecurity that could require us to modify our policies and practices in order to comply with new and evolving obligations relating to these matters. Information regarding risks associated with data security and privacy may be found in Part I, Item 1A of this Annual Report on Form 10- K under the heading “ Risk Factors. ” Environmental Laws and Regulations We are subject to numerous international, federal, state and local environmental laws, including provisions that regulate the purchase, use, distribution, and environmental impact of hazardous substances used in our operations, contained within our products and the packaging associated with our products. We are also subject to environmental laws applicable to our

manufacturing facilities and operations, including environmental health, safety and sustainability regulations. The number and rate at which these regulations are being proposed and implemented are increasing at the regional, country and local territorial levels, requiring greater diligence, governance and skills to manage. We may be required to incur significant costs to comply with existing and new laws and regulations in the future. Information regarding risks associated with environmental laws and regulations may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading “ Risk Factors. ”

Human Capital We believe our culture and commitment to employees provide unique value that benefits Align, its stockholders and the communities and other stakeholders we serve. Every employee, and every job, is important to our success and helps us achieve our purpose of transforming smiles and changing lives. Align is committed to building a global workforce with varied cultural backgrounds and life experiences. Fostering a culture of dignity, integrity, open dialogue, open- mindedness, compassion, fairness, recognition, and shared goals allows us to attract and retain the best talent, and provide a safe and supportive environment that allows our employees to excel. As of December 31, 2024, we had approximately 20, 945 employees, a decrease of approximately 3. 1 % and 9. 6 % over December 31, 2023, and December 31, 2022, respectively. The number of employees for each of the last five years and our employees’ roles as of December 31, 2024 are as follows: We are fundamentally a global organization with approximately 91 % of our employees located internationally, primarily in direct- labor roles in our manufacturing and clinical treatment planning facilities. Set forth in the following paragraphs are some of the most important elements of our culture and commitment to our employees.

Governance. Our commitment to improving the lives of our employees and the communities in which we live and work, including conducting our business ethically, responsibly and transparently through open and clear disclosures that allow us and others to hold us accountable, begins with our Board of Directors (“ Board ”) and management team. They set the tone for our organization by establishing and clearly communicating our core values of Agility, Customer and Accountability that inform our culture. Our Global Code of Conduct (“ Code ”) and quality policies are designed to enable us to operate with integrity and deliver superior treatment outcomes and experiences to patients. We seek to create an environment that values the health, safety and well- being of our teams, and we work to equip them with the knowledge and skills to serve our business and develop their careers. We believe that by effectively managing our business with these values as the foundation, we will drive long- term value for our stockholders and all stakeholders. As part of our Board ’ s commitment to our employees and communities, our Board has delegated oversight responsibility of our policies and practices that foster Align’ s sustainability and cultural initiatives, policies, practices, and programs to our Nominating and Governance Committee. Additionally, our Compensation and Human Capital Committee has oversight responsibilities of all human capital management strategies, programs and policies. Our Compensation and Human Capital Committee regularly reviews and discusses key performance indicators regarding human capital management that allow it to monitor trends on issues such as total headcount, employee hiring, recruiting, attrition, career development, compensation, benefits, workplace culture, and other measures of employee engagement and interest to management and the committee. We believe our success continues to be driven by our focus on integrating and welcoming employees across the globe and of all different backgrounds, orientations, beliefs, perspectives and capabilities into our workforce. Our employees bring a positive mix of ethnic and culturally diverse backgrounds to the 47 different countries in which we operate. Our largest population of employees work in Mexico followed by Costa Rica and China. Employees in the United States represent approximately 9 % of our global population. Our management team is comprised of individuals from varying countries and nationalities who are committed to promoting and encouraging the health and well- being of our employees at work, at home and in society in general. Our work culture is designed to create financial, health, career and personal benefits for our employees and organization. We sponsor cultural recognition events to increase awareness of inclusion and belonging, including its importance in creating an environment where every employee is safe, supported and can thrive. Our employees have also established and manage employee groups including employee resource groups which are based on shared characteristics or life experiences. These are open to all employees, including those who do not directly identify with other members.

Talent Recruitment and Engagement. We employ a variety of career development, employee benefits, compensation and other policies and programs designed to attract, develop and retain employees. We focus on building a talent pipeline that nurtures those early in their careers, encourages continuous learning and growth, and incentivizes employees to stay and contribute to our success over the long term. Our programs include early recruitment at high schools and universities, initiatives such as internships, co- ops, apprenticeships, and training programs, quarterly performance management check- ins focused on individual goals and commitment to values and conducting regular employee surveys to build trust and strengthen relationships. Our efforts have resulted in numerous awards for our positive work environment and culture. Some of the certifications, awards and recognitions recognized or received in 2024 and 2025 include: • Best Places to Work for Women in Korea • Dun & Bradstreet Top Tech Companies to Work for in Israel • Great Places to Work and Best Places to Work based on our employee- validated great workplaces in the following countries, Australia, Brazil, Canada, China, India, Italy, Korea, Singapore, Taiwan, Thailand, the United Kingdom, Vietnam and Raleigh, North Carolina (United States) • Forbes America’ s Dream Employers, America’ s Best Midsize Employers, America’ s Best Employers for Engineers, America’ s Best Employers for New Grads • Fortune, America’ s Most Innovative Companies • LinkedIn Top Companies, Brazil • Mercer China, Healthiest Workplace Award for Outstanding Women Care • Newsweek, America’ s Greatest Workplaces; Greatest Workplaces for Mental Wellbeing America • U. S. News & World Report- Best Companies to Work For and Best Companies to Work For in the Health Care Industry We believe it is imperative to provide a vibrant employee experience and we value our employees’ collective voices. Accordingly, we conduct employee surveys that utilizes a continuous employee listening strategy. to collect employee feedback critical to improving our culture. This listening strategy includes globally managed pulse

surveys, employee lifecycle surveys, and a self-service feature to support listening efforts. We use what we learn from the surveys to improve the employee experience, including enhancements to our workplaces, focus on employee connections, increased career development opportunities, support for relocated employees, and growth in our recognition programs and experiences. Our global response rates are consistently high, reflecting strong engagement by our employees.

Training and Professional Development. Training is an integral part of developing and retaining our employees and creating a culture of leadership within Align. Training at Align begins with our Code and our strong commitment to ethical business practices in all aspects of our operations. Every employee and contractor is required to review the Code and confirm they understand and will comply with it. We routinely reference the Code in presentations and as part of everyday operations. As a further part of our standard onboarding program, we train employees on important environmental health and safety topics to protect them and the environment. As a general practice, employees are trained to perform their jobs in accordance with all applicable statutory and regulatory requirements and that training is routinely refreshed and re-administered. At Align, we believe employees learn best when skill development is driven by the changing and immediate needs of our employees and by empowering all employees to take action and ownership of their careers. We also believe learning should be relevant and actionable as well as rooted in our purpose and values.

Develop @ Align enables our global employee population to access a diverse portfolio of approximately 1,800 self-directed courses in up to 80 languages. We also offer a full suite of custom leadership development programs, beginning with aspiring leaders, continuing with managers and directors, and culminating with executive development opportunities. We also recognize we must continually evolve by providing employees with the resources they need to continue to learn, grow, and thrive. To this end, we created Voyage. Voyage is a global initiative that offers a set of tools, resources and a new mindset, empowering employees to start thinking differently about career growth by embracing development opportunities in new and sometimes unexpected ways. Our Voyage Compass helps employees experience their career through four distinct lenses: Self, Networks, Experience and Skills. Since its launch in 2022, over 45 % of the population has interacted with Voyage, and there have been over 140,000 visits to the Voyage website. In addition to our navigation site, we annually host two Voyage Set Sail weeks, where we offer experiential learning for individuals and teams utilizing activities that keep professional development front and center in employees' minds.

Compensation and Benefits. Our benefit and compensation programs reflect the value and contributions our employees make. In addition to competitive base pay, we offer an assortment of benefits that vary by country, roles and contributions, including performance-based variable compensation programs, health and welfare benefit plans, retirement planning services and benefits, holiday and leave policies, equity participation programs such as our 2005 Annual Incentive Plan and Employee Stock Purchase Plan, and charitable and community service opportunities. We also offer discounts to our employees and their dependents who undergo Invisalign treatment. We are furthermore committed to pay equity practices. We exceed minimum pay requirements for our manufacturing employees and regularly review our pay equity practices globally and locally to address discrepancies.

Health, Wellness and Safety. Our employees' health and well-being is critical to our success and their continuing achievements. We therefore offer a wide variety of robust programs and initiatives designed to promote the overall health and welfare of all our employees and their families. Every year, we sponsor the Month of Wellness, a month dedicated to well-being and a worldwide movement fostering employee health across our organization. Throughout the Month of Wellness, employees participate in a variety of activities such as informational sessions and health fairs and receive useful resources aligned to our wellness pillars- mental resilience, physical well-being and healthy living, social / family connections, and financial wellness. This provides employees with a variety of meaningful ways to embrace wellness and well-being through mindfulness, meditation, nutrition and mental wellness activities, exercise, hikes, yoga, volunteer activities, financial education sessions, social events and stress management. Additionally, a primary objective is to prevent injuries and occupational diseases by focusing first and foremost on creating and maintaining safe environments. We have environmental, health, safety and sustainability personnel who are responsible for ensuring health and safety programs and processes are maintained and effective at each of our locations. Major worksites, such as our clear aligner fabrication sites, and large offices have dedicated Environmental Health and Safety ("EHS") departments which are dedicated to ensuring our health and safety programs are maintained while contributing Best Management Practices and general input to corporate-wide programs. Each EHS department is responsible for ensuring all employees at their location are properly trained on various EHS topics and at the appropriate frequencies. A training suite is determined for each employee depending on their responsibilities and function modeled off ISO 45001.

Community. We actively encourage employees to support charitable organizations by providing opportunities for volunteerism, team building, and donation and matching programs. In 2024, our employees continued to make us proud through their generosity and dedication, especially during our annual Month of Smiles initiative in October where we encourage them to make a difference individually and as teams through volunteer activities, charitable donations, fundraising, and intentional acts of goodness. In addition, through our Align Foundation, we support organizations whose visions closely align with our mission to improve smiles, supporting and educating teens, and empowering our customers through partnerships with learning institutions and foundations. Below are some of our key community initiatives in 2024:

- Since 2013 we have been a proud supporter of Operation Smile, a global medical nonprofit that has provided hundreds of thousands of free surgeries for people born with cleft lips and cleft palates in low and middle-income countries. For the fourth year, we sponsored Operation Smile's International Student Leadership Conference, a powerful opportunity for youth in high schools and colleges around the world to develop leadership skills and impact their communities. As part of our 2024 sponsorship, we provided full scholarships for 74 participants and students personally impacted with a cleft condition. In addition, we covered a portion of the conference fee for all students to make this opportunity more accessible for all attendees. As of December

31, 2024, we had donated approximately \$ 3. 0 million to Operation Smile. • As part of Align’ s commitment to improving oral health, we partnered with the INCAE Business School as they relaunched the CAHI Jeffe Fellowship in Health and Innovation to improve health services in Latin America. The CAHI Jeffe Fellowship brought together 23 leaders from six Latin American countries and focused on enhancing the quality, accessibility, and affordability of health services through a variety of programs. Align provided scholarships to two leaders from the program who focused on oral health education and expansion of dental health for low- income populations. • For 17 years we have supported America’ s ToothFairy, an organization with a mission to ensure underserved children in the United States have access to dental care and learn about oral health by supporting nonprofit clinics and community partners. As of December 31, 2024, we have provided almost \$ 2 million for the foundation’ s operational expenses and children’ s oral health programs. As Title Sponsor of the HERO Program since 2019, we have helped the program reach an estimated 2. 7 million children, caregivers, and parents. During America’ s ToothFairy’ s 2024 fiscal year, which ended June 30th, the HERO Program positively impacted more than 900, 000 children and caregivers, including: ◦ More than 600, 000 children — 33, 500 of whom speak a language other than English — who were reached with downloadable resources accessed from AmericasToothFairy. org, ◦ 43, 250 children taught with ToothFairy 101 @ Community Education Kits distributed to educators, public health workers, and oral health professionals, and ◦ Nearly 268, 000 people who were reached through two sponsored awareness campaigns that included educational materials and social media kits. We also provide product donations to the dental community to help patients in need of healthy, beautiful smiles. For more information on our charitable and community efforts, please refer to the Corporate Social Responsibility portion of our corporate website located at https://www.aligntech.com/about/corporate_social_responsibility. Available Information Our corporate website address is www.aligntech.com, and our investor relations website address is <http://investor.aligntech.com>. The information on or accessible through either of these websites is not incorporated by reference into this Annual Report on Form 10- K, and the above references to these website URLs are intended to be inactive textual references only. Our Annual Report on Form 10- K, Quarterly Reports on Form 10- Q, Current Reports on Form 8- K, our proxy statement on Schedule 14A for our annual stockholders’ meeting and amendments to reports filed pursuant to Sections 13 (a) and 15 (d) of the Exchange Act are available, free of charge, on our investor relations website as soon as reasonably practicable after we electronically file or furnish such material with the Securities and Exchange Commission (“ SEC ”). Further, the SEC maintains an internet site (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding our filings with the SEC. Information about our Executive Officers The following table sets forth certain information regarding our executive officers as of February 28, 2025: NameAgePositionPeriodJoseph M. Hogan67President and Chief Executive Officer of Align • Chief Executive Officer of ABB • Chief Executive Officer of GE Healthcare 2015- Present2008- 20132000- 2008John F. Morici58Chief Financial Officer and Executive Vice President, Global Finance of Align • Chief Financial Officer and Senior Vice President, Global Finance of Align • Chief Financial Officer of Align • EVP and Managing Director of NBC Universal North America Home Entertainment • CFO / Chief Operating Officer of NBC Universal North America Home Entertainment • Senior Vice President and Chief Financial Officer of NBC Universal North America Home Entertainment2022- Present2018- 20222016- 20182014- 20162011- 20142007- 2011Julie Coletti57Executive Vice President, Chief Legal and Regulatory Officer of Align • Senior Vice President, Chief Legal and Regulatory Officer of Align • Vice President, Associate General Counsel, Strategic Commercial Affairs of Align • Vice President, Global General Counsel and Chief Compliance Officer of Danaher • Vice President, Chief Legal Officer and Corporate Secretary of Bayer HealthCare’ s MEDRAD / Radiology and Interventional Division2022- Present2019- 20222018- 20192013- 20172007- 2013Stuart Hockridge53Executive Vice President, Global Human Resources of Align • Senior Vice President, Global Human Resources of Align • Vice President, Global Human Resources of Align • Vice President of Talent of Visa2022- Present2018- 20222016- 20182013- 2016

Item 1A. Risk Factors. Our business, reputation, results of operations, financial condition, **cash flows** and stock price can be affected by a number of factors, whether currently known or unknown, **or that we currently believe to be immaterial.** including those described below. When any one or more of these risks materialize from time to time, ~~our the Company’ s~~ business, reputation, results of operations, financial condition, **cash flows** and stock price can be materially and adversely affected. The risks below are not the only ones we face. Because of the following factors, as well as other factors affecting ~~our the Company’ s~~ results of operations and financial condition, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods. Therefore, you should review this section carefully, as well as our consolidated financial statements and notes thereto and other information appearing in this Annual Report on Form 10- K, for important information regarding these and other risks that may affect us. Additionally, you should consider these risk factors in connection with evaluating the forward- looking statements contained in this **Annual report Report on Form 10- K**.

Macroeconomic and External Risks Our business, financial condition and results of operations and financial performance depend on global and regional economic conditions. Inflation, fluctuations in **foreign** currency exchange rates, changes in consumer confidence and demand, ~~and~~ general economic weakness and ~~threats, or~~ actual **or potential slowdowns or** recessions ~~–~~ have and could in the future materially affect our business, ~~results of operations, and~~ financial condition, **and results of operations**. Macroeconomic conditions impact consumer confidence and discretionary spending, which can adversely affect demand for our products. Consumer spending habits are affected by, among other things, inflation, fluctuations in **foreign** currency exchange rates, **consumer confidence**, general economic weakness, ~~threats or~~ actual **or potential slowdowns or** recessions, pandemics, wars and military actions, employment levels, wages, debt obligations, discretionary income, interest rates, volatility in capital, ~~–~~ and ~~consumer confidence~~ and perceptions of current and future economic conditions. Macroeconomic conditions can, among other things, reduce or shift spending away from elective procedures, drive patients to pursue less costly

orthodontic treatments, decrease the number of orthodontic case starts, reduce patient traffic in dentists' offices, or reduce demand for dental services generally. Further, decreased demand for dental services can cause dentists and labs to postpone investments in capital equipment, such as intraoral scanners and CAD / CAM equipment and software. The declines in, or uncertain economic outlooks for, the **United States U.S.**, Chinese, European and certain other international economies have and **may continue to could in the future materially** adversely affect consumer and dental practice spending. Increases in the cost of fuel and energy, food and other essential items as well as higher interest rates have and **may continue to could in the future** reduce consumers' disposable income, which could cause a decrease in discretionary spending for **our products like ours**. Further, we cannot predict the **Inflation has and may continue to adversely** impact **of spending and trade activities, and may unpredictably impact global and regional economies, efforts Efforts** by central banks and federal, state and local governments to combat inflation, **which** could result in an economic recession or **have an slowdown or** adverse **adversely** impact **on** consumer spending **may** for a prolonged period of time. **Inflation continues to adversely impact spending and trade activities, causing unpredictable impacts on global and regional economies.** Higher inflation has **also and may continue to** increased **increase** domestic and international shipping costs, raw material prices, and labor rates, which **has could** adversely impacted **impact** the costs of producing, procuring and shipping our products. Our **ability to recover products or one or more of these** **the cost materials or components of our products may also be subject to tariffs imposed by the United States or other countries. We may not be able to fully mitigate the impact of the increases increased through costs or pass** price increases **on may continue to lag our customers**, resulting in downward pressure on our operating results. Attempts to offset cost increases with price increases may reduce sales, increase customer dissatisfaction or otherwise harm our reputation. Any of these events could materially affect our business **and operating, financial condition or** results **of operations**. We have significant international operations and sales and **we are therefore** exposed to fluctuations in foreign currencies that have **and may continue to** adversely impacted **impact** our business, **financial condition** or results of operations. Although the U. S. dollar is our reporting currency, a large portion of our **expenses, net revenues and expenses net income** are generated in foreign currencies. While we **forecast our balance sheet exposures to foreign currency fluctuations and** utilize **foreign currency** forward contracts to moderate the impact of exchange rate fluctuations on certain assets and liabilities, **these contracts our** hedging strategies **may not be successful, and eliminate our exposure to fluctuations in foreign** currency. **Currency** exchange rate fluctuations have and may continue to materially adversely **effect affect** our **operating results of operations** and cash flows. **In addition, our foreign currency exposure on assets, liabilities and cash flows that we do not hedge have and could in the future materially impact our financial results in periods when the U. S. dollar significantly fluctuates in relation to foreign currencies.** Our business, **financial condition and results of operations** could be impacted by geopolitical events, **tariffs, trade and other international disputes, war wars, military actions** and terrorism, or major public health crises. **Political Geopolitical** events, **tariffs, trade and other international disputes, war wars, military actions** and terrorism, or major public health crises have and could in the future harm or disrupt international commerce and the global economy, and could materially **adversely effect affect** our business **with** as well as our customers **and consumers**, suppliers, contract manufacturers, distributors, and other business partners. Such **risks include events have and could result in, among other things,** supply chain and trade disruptions, **changes in diplomatic and trade relationships, new tariffs and retaliatory tariffs, trade protection measures**, trade sanctions, **customs inquiries** or restrictions, boycotts, reduced consumer spending, government shut downs, **or** cyberattacks, energy shortages or power outages, energy rationing that adversely impacts our manufacturing facilities, rising fuel or rising costs of producing, procuring, and shipping our products, constraints, volatility or disruption in the financial markets, deaths or injuries to our employees, restrictions and shortages of food, water, shelter, and medical supplies, **data or information exchange, disruptions, interruptions or limitations in telecommunications- telecommunication failures services, critical systems or applications reliant on a stable and uninterrupted communications infrastructure, and protests that may impact delivery of our products to customers** or destruction of property. Tariffs **or proposed tariffs**, such as those on Chinese, Mexican, Canadian or other foreign goods, and **any retaliatory trade measures in responses- response** to the tariffs may increase the cost of our products and the components and raw materials used to make them. **Increased Specifically, we manufacture clear aligners in our facility in Mexico and ship them to the United States, primarily for our United States customers with the remainder eventually shipping to other international locations. Tariffs would result in additional costs could adversely for our products, which may impact operating our gross margin and, reduce demand for our products and adversely impact our gross margin. Foreign Countries countries** may also adopt **or rescind** other measures, such as controls on the import or export of goods, technology or data, **including personal data,** that **would could** adversely impact our operations and supply chains or limit our ability to offer **certain** products and services. These measures could require us to take various actions, including changing suppliers, **where we manufacture our products,** or restructuring business relationships. Complying with new or **changed-revised** trade restrictions **is may be** expensive, time-consuming **and,** disruptive to our **logistics and** operations, **and more costly for us and our customers**. Such restrictions **can may** be announced with little or no advance notice and we may be unable to effectively mitigate any adverse impacts. **Political** events, **trade and other international disputes, war, terrorism, or major public health crises involving key commercial, development or manufacturing markets such as China, Mexico, Israel, Europe, or other countries have and could again** materially impact our international operations. The impact to us, our employees and customers would be uncertain, particularly if emergency circumstances, armed conflicts or an escalation in political instability or violence, or viral out- breaks disrupt our product development, data or information exchange, payroll or banking operations, product or materials shipping by us or our suppliers. Our international operations would also be impacted by other unanticipated business disruptions, interruptions and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure **timely manner or at all**. Military conflicts and global pandemics have **and may in the future** materially adversely impacted **impact the** our global economies. For example, our commercial operations in **which** Russia

were impacted by the conflict in Ukraine and we **operate** were affected by the COVID-19 pandemic. Our iTero operations, headquartered in Israel, are close to areas that have been affected by ongoing violence and military action, **which in the Middle East and this may impact our employees and as well as our iTero business and operations**. Some employees and consultants in Israel have been called for military service in the current conflict in the Middle East and they may be absent for **certain an unknown period-periods** of time. Furthermore, our **facility-facilities** may be damaged or **our manufacturing capability or delivery schedules may be impacted as a result of the ongoing conflict. Our supply chains and demand for our products could be** impaired as a result of hostilities **which**, **export and import restrictions, sanctions or boycotts. These events** could disrupt ongoing operations and **impact our financial results. The conflict in the Middle East may materially impact the logistics,** timing and cost of shipping of our products, **and materials or** our ability to operate out of Israel, or lead to **sanctions or boycotts which could impact impacted areas** our sales and revenues. Additionally, the recent election in Taiwan and China's territorial conflicts with other neighboring countries may impact our operations and sales in China. We cannot predict the progress or outcome of these events or the reactions by governments, businesses or consumers **but they and each event could**, **individually or in the aggregate**, materially adversely affect our business, **financial condition**, and **operating results of operations**. Our operations may be impacted by natural disasters, which may become more frequent or severe as a result of climate change, and may adversely impact our business, **financial condition** and **operating results of operations**, as well as those of our customers and **consumers, suppliers, contract manufacturers, distributors and other business partners**. Natural disasters **such** can impact our operations as well as those of our customers and suppliers. Natural disasters include earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, **urban fires** and extreme weather conditions **that can** cause deaths, injuries, and **critical major public** health crises, power outages, property damage, restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures, materials scarcity, price volatility and other **adverse ramifications**. Climate change is likely to increase the frequency and severity of natural disasters and, consequently **consequences**, the risks to our operations and financial results. Our digital dental modeling and certain of our customer-facing operations are primarily processed in our facilities in Costa Rica, our iTero scanners are primarily manufactured in China and Israel, and our aligner molds and finished aligners are fabricated in China, Mexico and Poland. These zones are susceptible to natural disasters and their indirect effects. If a natural disaster occurs in a region where one of **these our** facilities or those of our customers or suppliers are located, our **or their** employees **or facilities** could be impacted, **valuable** research **could be** lost, and **our** ability to create treatment plans, respond to customer inquiries or manufacture and ship our **products aligners or intraoral scanners** could be compromised, causing significant **product and services delays and reputational harm**. The effects of climate **Climate** change on regional **could increase the frequency** and global economies **severity of natural disasters and** could change the supply, demand or availability of sources of energy or **other** resources material to **manufacturing** our products and operations and, **It could also** affect the availability or cost of **materials, natural resources and goods**, and services on which we and our suppliers, **contract manufacturers, distributors and other business partners** rely, **which could materially adversely impact our business, financial condition and results of operations**. Business and Industry Risks Demand for our products **and services** may not increase or may decrease **due to for many reasons, including** resistance to **non the innovative and business** traditional treatment methods **model- disruptive nature of some of our products and services**, which could have a material impact on our business, **financial condition** and **operating results of operations**. Our products **and services** require our customers **and consumers** to **forego** change from traditional treatment methods. For example, Invisalign treatment is a significant **change departure** from traditional orthodontic **metal** wires and brackets, and **our** customers and consumers may not find it cost-effective or preferable. A number of dental professionals believe Invisalign treatment is only appropriate for a limited percentage of patients. Additionally, our clear aligners and iTero products utilize digital technology and some dental professionals have **been** and may continue to resist moving to a digital platform. Increased acceptance of our products **and services** depends in part on the recommendations of dental professionals, **professional associations, societies and organizations**, as well as other factors, including efficacy, safety, ease of use, reliability, aesthetics, **third-party reimbursement** and price compared to competing products and **traditional** treatment methods. If demand for our products **or services** fails to increase, or decreases, our business, **including our financial condition** and **operating results of operations** may be **harmed materially adversely affected**. Our net revenues depend primarily on **our sales of the Invisalign system-System** and iTero **intraoral** scanners and declines in sales or **the** average selling price ("ASP") of these products may adversely affect net revenues, gross **margin profit**, and net income. Our net revenues **remain largely are primarily** dependent on sales of **our the Invisalign system-System** of clear aligners and iTero intraoral scanners. Of the two, we expect the Invisalign system-System **will to** continue to **represent** account for the majority of our net revenues, making **sales the widespread acceptance of it critical to our success. The ASPs of our products, particularly** the Invisalign system-System by orthodontists, GPs and consumers critical to our success. The average selling prices of our products, particularly the Invisalign system, are influenced by numerous factors, including the **type mix of product treatment packages, geographical mix, channel mix** and timing of products sold (particularly the timing **and quantity** of orders for additional clear aligners for certain Invisalign products) and foreign currency exchange rates. In addition, we sell **our** a number of products at different list prices **which and with varying shipping and handling charges or processing fees that** may differ **by** based on country. Our **ASPs** average selling prices for **our the Invisalign system-System** and iTero **intraoral** scanners have been **impacted in the past and may could in the future** be adversely affected in the future if: • we **offer** introduce new promotions, change existing promotions, or offer general or volume-based discount programs, product or services bundles, large account sales or consumer rebate programs; • participation in promotions or programs unexpectedly increases, decreases or changes demand in material ways; • our geographic, channel or product mix shifts to lower **priced** products or to products with a higher percentage of deferred revenue; • we decrease **prices or are unable to increase** prices on one or more products or services in response to increasing competitive pricing pressures; • we introduce new or change existing products or services, or modify how we market or sell any of our new or existing products

or services; • governments impose we modify our pricing regulations strategies for certain products or adjust pricing for certain items based on cancellation fees, shipping and handling charges or processing fees; • we participate in government tenders, such as volume- based procurement regulations in China; or • our critical accounting estimates materially used in the calculation of deferred revenue differ from actual results average selling prices. To stimulate product and services demand, we have a history of offering volume discounts, price reductions, and other promotions to targeted customers and consumers and releasing lower priced products. These promotional campaigns and lower- priced products have had, and may in the future have, unexpected and unintended consequences, including reduced net revenues, gross margins, operating margin profitability and average selling prices, net revenues, volume growth, and net income, ASPs and volume. Competition in the markets for our products and services is increasing and we expect aggressive competition from existing competitors, other companies that introduce new technologies or, products or services in the future, and customers who alone or with others create orthodontic appliances and solutions or other products or services that compete with us. The dental industry is experiencing immense and rapid digital transformation. While solutions such as our the Invisalign system System, iTero intraoral scanners and, CAD / CAM software and digital platform facilitate this transition, we face competition from companies that also seek to introduce new technologies and products and companies that remain dedicated to conventional traditional products. We may be unable to compete with these competitors or they may render our technology or products obsolete or economically unattractive, particularly as competitors incorporate AI and machine learning into new or existing services and technologies that facilitate changes in doctor- patient interactions, expectations and treatment workflows. We may be unable to devote adequate financial resources to develop or acquire new AI technologies and systems in the future and sufficiently meet evolving industry trends and consumer demands. The number and types of competitors we face are diverse and growing rapidly. The Invisalign system System competes primarily against traditional wires and brackets and increasingly with traditional metal wires and brackets and increasingly against clear aligners which are manufactured and distributed by new and existing market entrants and existing competitors, including traditional medical device companies, laboratories, startups and, in some cases, doctors and Dental Support Organizations (“DSOs”). Our competitors also include DTC companies that provide clear aligners using a remote- business model requiring little or no in- office care from trained and licensed doctors, and doctors and DSOs who manufacture custom aligners in their offices using 3D printing technology. Large consumer product companies may also start supplying orthodontic products. Orthodontists, GPs and DSOs have and may continue to sample competitive and alternative products and take advantage of competitive promotions and sale opportunities. Our iTero intraoral scanners are also facing increased competition from new and existing competitors. iTero Our scanners compete with polyvinyl siloxane (“PVS”) impressions and numerous new or existing intraoral scanners, as well as. They also compete with traditional bite wing 2D dental x- rays for detecting interproximal caries. We have and may continue to experience competition with our scanners by competitors who introduce products at lower prices or with functionality that better meets customer demand. If we are unable to compete effectively with existing products, existing competitors, new market entrants, or respond effectively to new technologies, our business, results of operations and financial condition, and results of operations could be materially adversely impacted. Our success depends on our ability to successfully develop, introduce, achieve market acceptance of, and manage new or improved products and services. Our success depends on our ability to quickly and profitably develop, manufacture, market, and obtain and maintain regulatory approval or clearance of new, improved or refurbished products and services along with improvements to existing products and services. We cannot assure successful development, sales or acceptance of our new or improved products and services. The extent and rate at which our new, improved or refurbished products or services achieve market acceptance and penetration depends on is a function of many variables factors, including our ability to: • successfully predict, timely innovate and, develop, and launch new or improved technologies, applications and, features, products preferred by and services to meet market demand and keep pace with changes in technology, customers’ demands and industry standards consumers that have features and functionality to meet the needs of patients; • successfully, and in a timely fashion, obtain regulatory approval or clearance of new and or improved products or services from government agencies such as the FDA and analogous agencies in other countries; • cost- effectively and efficiently develop, manufacture, quality test, market, dispose of, and sell new or improved products and services offerings, including localized versions for international markets; • properly forecast the amount and timing of new or improved product and services demand; • allocate our research and development funding to products and services with higher growth prospects; • ensure the compatibility of our technology, services and systems with those of our customers; • anticipate and rapidly innovate in response to new competitive products and services offerings and technologies; • differentiate our products and services from those of our competitors as well as other products and services in our own portfolio and successfully articulate the benefits to our potential customers; • design and manufacture products that achieve the clinical and practice outcomes we believe necessary for market acceptance; • manage the impact of nationalism or initiatives encouraging consumer purchases from domestic vendors; • qualify for third- party reimbursement for procedures involving our products or services; • offer attractive and competitive products, service services and subscription plans; • encourage customers to adopt new or improved technologies and provide the needed technical, sales and marketing support to make new or improved product and services launches successful; • manage government procurement program restrictions; and • source and receive quality raw materials or parts from our suppliers. If we fail to accurately predict the needs and preferences of customers and their patients, or fail to offer viable products or services, we may invest heavily in research and development that does not lead to significant revenues. Even if we successfully innovate and develop new or improved products and services product improvements, we may incur substantial costs doing so and our profitability may suffer. Introduction and acceptance of any products and services may take significant time and effort, particularly if they require doctor education and training to understand their benefits or doctors choose to withhold judgment on a product until patients complete their treatments. In addition, we periodically introduce new business and sales initiatives to meet customers’ needs and demands.

In general, our internal resources support these initiatives without clear indications they will prove successful or be without short-term execution challenges. Should these initiatives fail, our business, **results of operations and financial condition and results of operations** could be materially **adversely** impacted. We may invest in or acquire other businesses, products, technologies, or other assets which may require significant management attention, disrupt our business, dilute stockholder value **and or** adversely affect our **business, financial condition and results of operations**. **We** Periodically, we have and may in the future acquire, or make investments in, companies, technologies, or other assets. Alternatively, we may be unable to find suitable investment or acquisition opportunities or be unable to complete investments or acquisitions on favorable terms. If we make **such** investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve desired synergies, **and integration.** **Investments** or acquisitions we complete could be viewed negatively **by our customers, securities analysts and investors.** **Opposition to acquisitions** may lead to negative ratings by analysts or investors, **or** give rise to stockholder objections or **result in stockholder activism,** any of which could disrupt our operations or harm our stock price. Moreover, to the extent we make strategic investments, the companies in which we invest may fail or we may ultimately own less than a majority of the outstanding shares of the company and be unable to control or have significant influence over critical issues that could harm the value of our investment. **We** As an organization we do not have a history of significant **acquisitions or integrating their operations and cultures with our own.** As such, we are subject to various risks when making a strategic investment or acquisition **and integrating the operations and cultures of acquired businesses within our own,** which could materially impact our business, **financial condition** or results of operations, including that we may: • fail to perform proper due diligence and inherit unexpected material issues or assets, including intellectual property (“IP”) or other litigation or ongoing investigations, accounting irregularities or compliance liabilities; • fail to comply with regulations, governmental orders or decrees; • experience **information technology (“IT”)** security and privacy compliance issues; • invest in companies that generate net losses or are slow or fail to develop; • not realize a positive return on **our** investment or determine that **our** investments have declined in value, **necessitating we which could potentially require record-keeping** impairments **such as future impairments of intangible assets and goodwill;** • **have need** to pay cash, incur debt or issue equity securities to pay for an acquisition, adversely affecting our liquidity, financial condition or the **value trading price** of our common stock - **The sale of equity or issuance of debt to finance any acquisition could result in dilution to our stockholders. The occurrence of indebtedness would result in increased fixed obligations and could also include covenants or other restrictions that impede our ability to manage our operations;** • find it difficult to implement and harmonize company-wide financial reporting, forecasting and budgeting, accounting, billing, IT and other systems due to inconsistencies in standards, internal controls, procedures and policies; • require significant time and resources to effectuate the integration; • fail to retain key personnel or harm our existing culture or the culture of an acquired entity; • not realize material portions of the expected synergies and benefits of the investment or acquisition; or • unsuccessfully evaluate or utilize the acquired technology or acquired company’s know-how or fail to successfully integrate the technologies acquired. Operational Risks Our operating results have and will continue to fluctuate in the future, which makes predicting the timing and amount of customer demand, **and** our revenues, costs, and expenditures difficult. Our quarterly and annual operating results have and will continue to fluctuate for a variety of reasons. Some of the factors that have **historically,** and could in the future, cause our operating results to fluctuate include: • changes in consumer and doctor demand; • **higher changes in** manufacturing, **packaging,** delivery and inventory costs; • the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due; • **our ability to collect payments;** • **our acceptance of longer customer payment cycles;** • changes in the timing of revenue recognition and our **ASPs average selling prices;** • seasonal fluctuations; • **geographic, channel or product mix shifts to lower priced products or to products with a higher percentage of deferred revenue;** • improvements to or changes in our products, capabilities or technologies that replace or shorten the life cycles of legacy products or cause customers to defer or stop purchasing legacy products until new products become available; • **changes longer customer payment cycles and greater difficulty in accounts receivable collection;** • costs and expenditures, including in connection with new treatment planning and fabrication facilities, **and** the hiring and deployment of personnel **and litigation;** • the timing of clear aligner treatment order **submission submissions,** acceptance, processing and fulfillment, which can cause fluctuations in our backlog; and • timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows. If we **underestimate fail to accurately predict** product demand, **it we** may **exceed not have the appropriate level of** our manufacturing capacity or that of one or more of our suppliers, **staffing,** we may be understaffed and we may not have sufficient **materials, components, space, equipment** for **or finished** production **products**. Specifically, our manufacturing process relies on sophisticated computer software and requires new technicians to undergo a long training process, often 120 days or longer. **Additionally** As a result, if we fail to accurately predict demand, we may have an insufficient number of trained technicians to timely manufacture and deliver products to meet customers’ expectations, which could damage our relationships with our existing customers or harm our ability to attract new customers. Specifically, production levels for our iTero **intraoral** scanners are generally set based on forecasts and historic product demand and we often place orders with suppliers for materials, components **and,** sub-assemblies (“materials and components”) as well as finished products weeks or more in advance of projected customer orders. Conversely, if we overestimate customer demand, we may have excessive staffing, materials, components and finished products, or capacity. If we **do not** hire and train **too many the appropriate number of** technicians in anticipation of demand that does, **our costs and expenditures may** not **align with** materialize or materializes slower than anticipated, our costs and expenditures may outpace our revenues or revenue growth, **harming our gross margin and financial results.** Additionally, to secure supplies for production of products, we periodically enter into non-cancelable minimum purchase commitments with vendors, which could impact our ability to adjust inventory for declining demand. **In addition** If product demand decreases or increases more than forecast, we may be required to purchase or lease additional or larger facilities and additional equipment, or **to manage demand. If** we **fail** may be unable to timely fulfill customer **manufacture and deliver products to meet** demand

~~Responding to unanticipated changes in demand may take time, lower~~ **this could damage our relationships with existing customers gross margin, inhibit sales or harm our reputation ability to attract new customers and adversely affect our business, financial condition and results of operations.** We may make business decisions that adversely affect our operating results such as modifications to our pricing policies and payment terms, promotions, development efforts, product releases, business structure or operations. ~~Most~~ **The majority** of our expenses, such as employee compensation and lease obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on ~~our~~ expectations for future revenues. As a result, if our net revenues for a particular period are below expectations, we may be unable to timely or effectively reduce spending to offset any ~~net revenues shortfall~~ **shortfalls**. **This variability and unpredictability could also result in our failing to meet the expectations of industry, financial analysts or investors.** We are subject to operating risks, including excess or constrained capacity and operational inefficiencies, which could adversely affect our results of operations. We are subject to operating risks, including excess or constrained capacity, **operational inefficiencies** and pressure on our internal systems, personnel and suppliers. To manage current and anticipated future operations effectively, we must continually implement and improve our operational, financial and management information systems, hire, train, motivate, manage and retain employees, and ensure our suppliers remain diverse and capable of meeting demand for the systems, raw materials, parts and components essential to product manufacturing and delivery. We may fail to balance near-term efforts to meet existing demand with future demand, including adding personnel, creating scalable, secure and robust systems and operations, and automating processes for long-term efficiencies. Production of ~~our the~~ **Invisalign system System** and iTero **intraoral** scanners could also be limited by capacity constraints due to a variety of factors, including labor shortages, shipping delays, our dependency on third-party vendors for key materials, parts, components and equipment, **the quality of or changes in product components**, and limited production yields. Any such failure could materially impact our business, **financial condition and results of operations and prospects**. Additionally, we have established treatment planning and manufacturing facilities closer to our international customers to provide better experiences, create efficiencies, and provide redundancy should other facilities become unavailable. If ~~a~~ **one of these facility facilities** is temporarily, partially or fully shut down, we may be unable to timely fulfill orders, which may negatively impact our **reputation, business, financial condition and results of operations**, ~~reputation and overall business~~. Our ~~products and~~ IT systems are critical to our business. Issues with ~~product development or enhancements~~, IT system and software integration, implementation, updates, and upgrades, **or third-party software** have previously and could again in the future disrupt our operations and have a material impact on our business, our reputation, and operating results. We rely on the efficient, uninterrupted, and secure operation of ~~our~~ complex IT systems and are dependent on key third-party software embedded in ~~our products and~~ IT systems as well as third-party hosted IT systems to support our operations, **including third-party cloud platforms**. All software and IT systems are vulnerable to damage, cybersecurity attacks, ~~or interruption~~ **interruptions or other disruptions** from a variety of sources, **including rapidly developing AI technologies**. To effectively manage and improve our operations, our IT systems and applications require an ongoing commitment of significant expenditures and resources to maintain, protect, upgrade, enhance, and restore existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards, **including privacy, security and data protection laws and regulations**, increasingly sophisticated cybersecurity threats, and changing customer preferences. Usage of online and hosted technology platforms by us, our customers, and suppliers, including remote working, teledentistry, and new or expanded use of online service platforms, products, and solutions such as doctor, consumer, and patient apps have increased the demands on and risks to our IT systems and personnel. Moreover, we continue to transform ~~certain~~ business processes, extend established processes to new subsidiaries, and ~~or~~ implement additional functionality in our enterprise resource planning, product development, manufacturing, and other software and IT systems ~~which~~. **This** entails certain risks, including ~~operational disruption~~ **disruptions of our operations**, such as our ability to **continue develop** **developing and update updating** products that are **while addressing safe safety** and **secure security**, track orders and timely ship products, manage our supply chain, and aggregate financial and operational data. Failure to adequately protect and maintain the integrity of our products and ~~our~~ IT systems and those of our suppliers and customers may materially impact our **business, financial position condition**, and results of operations and cash flows. We first introduced **including increased security risks, errors and malfunctions that may be irreparable or released difficult to repair**. The discovery of a defect, error, or security vulnerability in our products, software applications or IT systems, incompatibility with customers' computer operating systems and hardware configurations with a new release or upgraded version or the failure of our products or primary IT systems, ~~which we are unable to cure in a timely fashion~~, may cause adverse consequences. ~~These may include~~ **including** ~~delays~~ **delay** or loss of revenues, significant remediation costs, **delay in** market acceptance ~~delays, data damage, loss of data~~, or ~~unavailability, unintended disclosure or other processing of financial, health or other personal information relating to individuals of our customers or their patients~~, product recalls, **damage to our reputation**, loss of market share or increased service costs, any of which have a **material effect on our reputation, business, financial condition or results of our operations and the operations of our customers or our business partners**. Products in our Systems and Services segment, such as our iTero intraoral scanners, are subject to software and hardware risks that, if improperly managed, could have a material adverse impact on our business and financial results. The success of our Systems and Services segment depends on the **quality and reliability of our products**. We face software and hardware risks related to the manufacturing, design, **quality and safety of our** complex, global iTero scanner-installed base of **iTero intraoral scanners, which** older and newer models. These models are continually updated to add, expand, or improve features with new hardware **we manufacture or components that we source, to integrate new or existing software or other components manufactured by third parties**, or to provide repair or replacement parts, **any of which may contain errors or exhibit failures, especially when products are first introduced**. We have experienced hardware issues in the past and may in the future, including issues relating to manufacturing, design, quality, or safety, of which we become aware only after products or changes have been introduced into

the market. We also have not been and may continue to be unable to ensure that third party components or changes to them will be **completely** compatible with, or will not have a negative impact on the functionality of, our iTero **intraoral** scanners. As a, **which could** result in, there have been and may be widespread failures of our iTero **intraoral** scanners or we may experience epidemic failures of our iTero scanners to perform as anticipated. **Previously** **Additionally**, we have **the third- party software integrated into or interoperable with our iTero intraoral scanners will routinely reach end of life, and as a consequence, certain applications and models may be exposed to additional vulnerabilities, including security risks, errors, and malfunctions that may be irreparable or difficult to repair. We may** not been and in the future may not be prepared for, or have the infrastructure to, timely and adequately remediate or implement corrective measures for such failures, including due to **reliance** our dependency on third -party providers or suppliers. Consequently, any remediation may be time- consuming and difficult to achieve, which may materially impact our customers and business partners, damage our reputation, and result in lost business and revenue opportunities, and could be materially costly. **If our products experience component aging, errors, or performance problems, or do not otherwise satisfy our stringent quality processes and controls we may choose to or be compelled to recall certain products, which may include, product withdrawals from the market, labeling changes, design changes, customer notifications, and notifications to global regulatory bodies**. A significant portion of our clear aligner production is dependent on digital scans from our globally dispersed and decentralized installed base of iTero and third- party intraoral scanners. Failures of all or any portion of our or third- party software or other components or systems to interoperate with iTero or third- party **intraoral** scanners, termination of interoperability with third- party **intraoral** scanners, malware or ransomware attacks, product or system vulnerabilities or defects, interference or disruptions for us, our customers, labs or other business partners in the use of our products or the transmission or processing of data needed for the use or ordering of our products, or a system **outage** **outages for any reason, regardless of cause**, have harmed our operations previously and in the future could materially and adversely affect our ability to accept scans, manufacture clear aligners or restorative procedures or treatments and services, or otherwise service our customers. Any of these events **could** harm our sales, damage our reputation, adversely impact our strategic partners, or result in **claims, demands**, litigation. **Additionally**, we continuously upgrade and issue new releases of software applications upon which customer facing manufacturing and treatment planning operations depend. Software applications and products containing software frequently contain errors or defects, especially when first introduced or released. **Additionally, the third- party software integrated into or interoperable with our products and services will routinely reach end of life, and as a consequence, certain applications and models of our iTero scanners may be exposed to additional vulnerabilities-- liabilities, including increased security risks, errors and..... or increased service costs, any of which could have a material effect on our reputation,** business, financial condition or results of our operations and the operations of our customers or our business partners. We are highly dependent on third- party suppliers, some of whom are sole source suppliers, for certain key machines, components and materials, and our business, **financial condition** and operating results of **operations** could be **harmed** **materially adversely affected** if supply is restricted or ends, or if the price of raw materials **materially** used in our manufacturing process increases. We are highly dependent on our supply chain, particularly manufacturers of specialized **and customized** scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our iTero **intraoral** scanners. We maintain single **and sole** supply relationships for many of these machines and materials. By using single **and sole** suppliers in limited locations for materials and manufacturing, we are exposed to multiple supply chain vulnerabilities. **We are reliant upon manufacturers that we contract with for quality and stability and any failures on their part may have an impact on our ability to supply our products**. Because of our dependence on our suppliers, changes in key relationships can materially disrupt our supply chain. For instance, we may be unable to quickly establish or qualify replacement suppliers **creating, which could create** production interruptions, delays and inefficiencies. Finding substitute manufacturers may be expensive, time-consuming or impossible and could result in significant interruptions in the supply of one or more products, product retesting or additional product registration, causing us to lose revenues and damage customer relationships. Technology changes by our service providers, vendors, and other third parties could disrupt access to required manufacturing capacity or require expensive, time- consuming development efforts to adapt and integrate new equipment or processes. In the event of technology changes, delivery delays, labor stoppages or shortages, or **shortages of, or** increases in price for these items, sales may decrease and our business and prospects may be harmed. We use distributors for a portion of the importation, marketing and sales of our products and services, which exposes us to risks to our sales, operations and reputation, including the risk that these distributors do not comply with applicable laws or our internal procedures. In addition to our direct sales force, we have and expect to continue to use distributors to import, market, sell, service and support our products **and services**. Our distribution agreements are generally non- exclusive and terminable by either party with customary notice. If alternative distributors cannot be quickly found and trained in the use, marketing, sales and support of our products and services, our revenues and ability to sell or service our products **and services** in key markets could be adversely affected. These distributors may also choose to sell alternative or competing products or services. In addition, we may be held responsible for the actions of these distributors **and**, their employees and agents for compliance with laws and regulations, including fair competition, bribery and corruption, **trade import and export** compliance, safety, data privacy, **false advertising or unfair and deceptive trade practices**, and marketing and sales activities. The conduct of these distributors **also may impacts-- impact** our reputation and our brand **and if they**. **If our distributors** fail to satisfy customers, our reputation and brand loyalty could be harmed. A distributor may also affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if it holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for non- compliance or prevents us from taking control of any such authorization. It may be difficult, expensive, and time- consuming for us to re- establish market access or regulatory compliance. A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could disrupt our supply chain and impact our

operating and financial results. We ~~are dependent~~ **depend** on commercial freight carriers, primarily **UPS-United Parcel Service, Inc.**, to deliver our products. If the operations of **commercial freight** carriers are disrupted or we fail to mitigate any disruptions, we may be unable to timely deliver products to our customers who may choose alternative products, causing our net revenues and gross margin to decline, possibly materially. Moreover, when fuel costs increase, our freight costs generally do ~~so~~ as well. In addition, we earn an increasingly larger portion of our total revenues from international sales, which carry higher shipping costs that negatively impact our gross margin and results of operations. If freight costs materially increase and we are unable to successfully pass all or significant portions of the increases along to our customers, or we cannot otherwise offset such increases, our gross margin and financial results could be materially affected. Our success depends on our personnel. If we cannot attract, motivate, train or retain personnel, it ~~may~~ **will** be difficult to achieve our strategic priorities, **which could** materially ~~effecting~~ **adversely affect** our **business, financial condition and** results of operations. We are highly dependent on the talent and efforts of our personnel. We strive to retain our personnel by providing competitive compensation and benefits, development opportunities and training, flexible work options ~~;~~ and an inclusive corporate culture. However, competition for highly- skilled personnel **, particularly technical and digital talent,** is intense ~~;~~ **particularly technical and digital talent,** and our competitors have and are likely to continue to recruit our personnel. Our compensation and benefit arrangements may not successfully attract new ~~employees,~~ **personnel or** retain ~~or~~ **and** motivate existing ~~employees,~~ **personnel**. In addition, other internal and external factors can impact our ability to hire and retain talent, including insufficient advancement or career opportunities **, in office or hybrid work policies** and restrictive immigration policies. The loss of any key personnel, particularly executive management, research and development ~~personnel,~~ or sales personnel, could harm our business and prospects and impede the achievement of our research and development, operational or strategic objectives. We provide significant training to our personnel and our business will be harmed if our training fails to properly prepare them to perform the work required, we are unable to successfully instill technical expertise in new and existing personnel **,** or if our techniques prove unsuccessful or are not cost- effective. Moreover, for certain roles, this training and experience can make key personnel, such as our sales personnel, highly desirable to competitors and lead to increased attrition. It can take **12** ~~up to twelve~~ months or more to train sales representatives to successfully market and sell our products **and services** and for them to establish strong customer relationships. The loss of the services and knowledge of our highly- skilled ~~employees,~~ **personnel** may significantly delay or prevent the achievement of our development ~~and business,~~ **operational or strategic** objectives. Additionally, seamless leadership transitions for key positions ~~is~~ **are** critical to sustaining our culture and organizational success. If our succession planning is ineffective, it could adversely impact our business. We ~~continually continue to~~ assess key personnel we believe **are** essential to our long- term success. Moreover, future organizational changes may cause ~~employee~~ attrition rates to increase. If we fail to effectively manage any organizational or strategic changes, our financial condition, results of operations, and reputation, as well as our ability to successfully attract, motivate **,** and retain key ~~employees,~~ **personnel**, may be ~~harmed~~ **adversely affected**. We have adopted a hybrid work schedule in many of our offices, allowing employees to collaborate and connect with others several days each week while providing the option to work remotely other days. This hybrid work approach may create challenges with maintaining our corporate culture, employee satisfaction **,** and hiring, promotion ~~;~~ and retention. We believe a key to our success has been the culture we have created that emphasizes a shared vision and **core** values ~~of focusing on~~ **Agility**, ~~customer~~ **Customer** success and ~~accountability~~ **Accountability**. We have experienced and may continue to experience ~~in the future,~~ difficulties attracting and retaining ~~employees,~~ **personnel** that meet the qualifications, experience, compliance mindset and values we expect. If we cannot attract and retain personnel that meet our selection criteria or relax our standards, our corporate culture, ability to achieve our strategic objectives ~~;~~ and our compliance with obligations under our internal controls and other requirements may be harmed. This could have a material adverse effect on our results of operations and our ability to maintain market share. We have ~~employees,~~ **personnel** represented by works councils **and trade unions** in certain countries and others that may be or may become eligible to be represented by works councils, trade unions and other employee associations. Labor disputes and work stoppages involving our ~~employees,~~ **personnel** may disrupt our operations and could materially impact our results or operations. We depend on our marketing activities to deepen our market penetration and raise awareness of our brands ~~and,~~ products **, and services**, which may prove unsuccessful or may become less effective or more costly to maintain in the long term. Our marketing efforts and costs are significant and include national and regional campaigns in multiple countries involving television, print ~~and,~~ social media and alliances with professional sports teams, social media influencers and other strategic partners. There is no assurance our advertising campaigns will achieve the **desired** returns on advertising spend ~~desired,~~ increase brand ~~or,~~ product **or services** awareness sufficiently or generate goodwill and positive reputational goals **, or that we will be able to maintain commercial relationships with social media influencers and other strategic partners**. Moreover, should any entity or individual endorsing us ~~or,~~ our products **or services** take actions, make or publish statements in support of, or lend support to events or causes which are perceived by a portion of society negatively, our sponsorships or support of these entities or individuals may be questioned, our products **and services** boycotted ~~;~~ and our reputation harmed, any of which could materially ~~effect~~ **affect** our **business, financial condition and** results **of operations and business overall**. In addition, ~~various~~ **many** countries prohibit certain types of marketing activities. For example, some countries restrict direct to consumer advertising of medical devices. We have ~~in the past~~ and may ~~again~~ in the future be alleged to violate marketing restrictions and be ordered to stop certain marketing activities or prevented from selling our products **and services**. Moreover, competitors do not always follow these restrictions, ~~creating~~ **which can create** an unfair advantage and ~~making~~ **make** it more difficult and costly to compete. Additionally, we rely heavily on data generated from our campaigns to target specific audiences and evaluate their effectiveness, particularly data generated from internet activities on mobile devices. To obtain this data, we are dependent on third parties and popular mobile operating systems, networks, technologies, products ~~;~~ and standards we do not control, such as the Android and iOS operating systems, and mobile browsers. Changes in such systems that degrade or eliminate our ability to target or measure the results of ads or increase costs to target audiences could adversely affect our

campaigns. Operating systems could also include data privacy settings that **may** limit our ability to interpret, target and measure ads effectively. ~~We have been incorporating and continue.....~~ risks, reputational harm and legal liability. Legal, Regulatory and Compliance Risks We are subject to antitrust and competition regulations, litigation and enforcement that may result in fines, penalties, restrictions on our business practices, and product, **services** or operational changes which could materially impact our business, **financial condition and results of operations**. We currently are and may in the future be subject to antitrust, competition or unfair competition -related investigations, enforcement actions or claims by governmental agencies, competitors, consumers, customers, ~~and~~ others which, even if unfounded, could cause us to incur substantial costs, enter into settlements, ~~consents-~~ **consent decrees**, be subject to judgments, involve negative publicity, ~~and~~ divert management time and attention, which may materially impact our **business, financial condition and** results of operations. Resolving these matters may require us to change our business practices in materially adverse ways. Governments and regulators are actively developing new competition laws and regulations aimed at the technology sector, AI and digital platforms, ~~and~~ **coordinating global** activities ~~globally~~ **and expansion**, including in large markets such as the **EU United States, the European Union U. S.,** and China. Government regulatory actions and court decisions may result in fines or hinder our ability to provide certain benefits to our **customers and** consumers, reducing the attractiveness of our products, **services** and the **net** revenue derived from them. These actions and decisions may also hinder our ability to pursue certain mergers, acquisitions, business combinations, **investments** or other transactions. ~~We are currently subject to two antitrust actions with jury trials scheduled to begin on May 13, 2024, and January 21, 2025. We believe the plaintiffs' claims are without merit in each of these actions, but we will likely incur costs in connection with these trials and with our defense, and there is a risk that we will be subject to adverse judgments or negative publicity.~~ Failure to obtain or maintain approvals or comply with regulations regarding our products or services or those of our suppliers could materially harm our sales, result in substantial penalties and fines, **interrupt our supply chain** and cause harm to our reputation. We and many of our healthcare provider customers, suppliers and distributors are subject to extensive and frequently changing regulations under numerous federal, state, local, ~~and~~ foreign laws, including those regulating: • the storage, transmission ~~and~~, disclosure, **and other processing of, and security measures with respect to,** personal, financial ~~and~~ medical information as well as healthcare records; • **processing and use of children's personal and health data; • websites and application advertising, including that involving the use of cookies or involving the collection, use, disclosure, or other processing of data relating to individuals for marketing purposes; •** prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products **and services**; and • the design, manufacture, marketing and advertising of our products **and services**. The healthcare and technology markets are also highly regulated and subject to ~~changing~~ **evolving** political, economic and regulatory influences. Global regulators are expanding and changing regulations and guidance for products **and services**, which can limit ~~the their~~ potential benefits of products ~~of products~~ and cause protracted review timelines for new products **and services**. Our critical third- party vendors and service providers are ~~similarly~~ **similarly** subject to ~~various similar~~ regulations. Our failure or the failure of our suppliers, customers, advertisers, **consultants**, and influencers to strictly adhere to clearances or approvals in the labeling, marketing and sales of our products and services could subject us to claims or litigation, including allegations of false or misleading advertising or violations of laws or regulations, which may result in costly investigations, fines, penalties, as well as material judgments, settlements or decrees. We are also subject to complex, new and ~~changing~~ **evolving** environmental, health and safety regulations. There can be no assurance we will adequately address the ~~business~~ risks associated with the implementation and compliance with such laws and our internal processes and procedures to comply with such laws or that we will be able to take advantage of any resulting business opportunities. Furthermore, before we can sell a new medical device or market a new use of, or claim for, an existing product, we frequently must obtain **regulatory** clearance or approval ~~to do so~~. For instance, in the **United States U. S.,** FDA regulations are wide -ranging and govern, among other things, product design, product materials, development, manufacturing and testing, product labeling and product storage. It takes significant time, effort, ~~and~~ expense to obtain and maintain clearances and approvals of products and services, and there is no guarantee we will timely succeed, if at all, in the countries in which we do business. In other countries, the requirements, time, effort and expense to obtain and maintain clearances may differ materially ~~from those of the FDA~~. Moreover, these laws may change, resulting in additional time, expense or loss of market access. If ~~the~~ requirements to market our products or services are delayed, we may be unable to offer them in markets we deem important. Additionally, failure to comply with applicable regulatory requirements could result in enforcement actions with sanctions, ~~including, among other things,~~ fines, civil penalties and criminal prosecution. Delays or failures to obtain or maintain regulatory approvals, clearances or to comply with regulatory requirements may materially ~~harm~~ **adversely affect** our domestic or international operations, and adversely impact our business. We and certain of our third- party vendors must also comply with and adhere to facility registration and product listing requirements for Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Failure to satisfactorily correct an adverse inspection finding or ~~to comply with applicable~~ **manufacturing** regulations can result in enforcement actions, or ~~we may be required-~~ **require us** to find alternative manufacturers, which could be a long and costly process and may cause reputational harm. Enforcement actions by regulators could have a material effect on our business, **financial condition and results of operations**. We are also subject to anti- corruption and anti- bribery (" ABAC ") laws such as the Foreign Corrupt Practices Act (" FCPA ") and the U. K. Bribery Act of 2010, which generally prohibit payments to foreign officials for the purpose of obtaining or maintaining business, securing an advantage and directing business to another. To comply with ABAC laws, regulators require ~~that~~ we maintain accurate books and records and a system of internal accounting controls. Under the FCPA, we may be held liable for corruption by directors, officers, employees, agents, or other strategic or local partners, **intermediaries** or representatives **acting on our behalf**. ~~In addition, while~~ **While** we have policies **and procedures** requiring compliance with applicable laws and regulations and we provide ~~significant~~ **significant** training to foster compliance, our employees, third parties acting on our behalf, ~~and~~ customers may not ~~properly~~ **and procedures** or

applicable laws or regulations, including the use of certain electronic communications and maintaining accurate books and records. If our personnel or the personnel of our agents or suppliers fail to comply with any laws, regulations, policies or procedures, or we fail to audit and enforce compliance, our reputation may be harmed, we may lose customers ~~or~~ revenues ~~or~~ we may face regulatory investigations, actions and fines. **In June 2024, the U. S. Supreme Court reversed its longstanding approach to evaluating administrative rulemaking under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. There may be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the courts. For example, this decision may result in more companies suing the FDA to challenge its longstanding decisions and policies, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit.** Security breaches, data breaches, cybersecurity attacks, other cybersecurity incidents, or the failure to comply with privacy, security and data protection laws could materially **adversely** impact our operations ~~and~~ patient care ~~could suffer~~, **and** we could be liable for damages, and our **reputation, business, financial condition and results of** operations ~~and reputation~~ could be harmed. We retain confidential **employee, applicant and** customer personal, **health** and financial, ~~patient health~~ and our own proprietary information and data essential to our ~~business~~ operations. We rely on the effectiveness of our IT systems, ~~our~~ policies and contracts and **the** policies of our third- party vendors, ~~and the their~~ IT systems of our service providers and other third parties to safeguard ~~the~~ information and data. Additionally, our ~~success~~ **cybersecurity controls depends** ~~depend~~ on our **customers** ~~healthcare providers~~, many of whom are individual or small ~~operations~~ **healthcare providers** with limited IT experience and inadequate or untested security protocols, to successfully manage data privacy and security requirements. It is critical that the facilities, infrastructure and IT systems on which we depend and the products **and services** we develop remain secure and be perceived ~~by the marketplace and our customers~~ as secure. Despite the implementation of security features in our products **and services** and security measures in our IT systems, we and our service providers, third- party vendors ~~and other third parties~~ **are** ~~could be~~ targeted by or subject to physical break- ins, computer viruses and other malicious code, unauthorized or fraudulent access, programming errors or other technical malfunctions, hacking ~~or~~ **attacks, phishing and other social engineering** attacks, malware, ransomware, employee error or malfeasance, cybersecurity attacks, **malicious code**, and other breaches of, ~~or~~ **incidents impacting**, IT systems or similar **malicious or otherwise** disruptive actions, including by organized groups and nation- state actors, **which may disrupt or limit the availability of, or result in damage to, our IT systems and result in loss or unavailability of, damage to, or the unauthorized acquisition, use, disclosure, or other processing of confidential information**. For example, we have experienced, and may again experience in the future, cybersecurity incidents, **data incidents**, and unauthorized internal employee exfiltration of ~~company~~ information. **This risk is exacerbated with the advancement of technologies like AI, which malicious third parties can use to create new, more sophisticated and more frequent or other attacks. There can be no assurance our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information or any other information we maintain or otherwise process**. Further, the frequency and sophistication of third- party cybersecurity attacks ~~is~~ **are** increasing. Significant service disruptions, breaches ~~in~~, **incidents, interruptions or other disruptive events impacting** our infrastructure and IT systems, ~~or~~ other cybersecurity incidents, ~~or~~ **any belief or reporting that any of the foregoing has occurred**, could expose us to ~~litigation or~~ regulatory investigations, ~~or~~ **other proceedings, private claims, demands, and litigation**, impair our reputation and competitive position, ~~be distracting~~ ~~---~~ **distract** ~~to~~ management ~~and~~ require significant time and resources to address. Legal or regulatory action against us could prevent us from resolving issues quickly or force us to resolve them in unanticipated ways, cause us to incur significant expense and damages, or result in orders forcing us to cease operations or modify our business practices in ways that materially limit or restrict ~~the capabilities of~~ our products and services. Concerns over our **practices with respect to** privacy ~~practices~~, **data protection, data governance, and cybersecurity** could adversely affect **our reputation** ~~others' perception of us~~ and deter customers and ~~patients~~ **consumers** from using our products **and services**. In addition, patient care could suffer, and we could be liable if our products, **services** or IT systems fail to timely deliver accurate and complete information. We have cybersecurity and other forms of insurance coverage related to ~~cyberattacks~~ ~~a cyber attacks~~, breaches, and other incidents or security problems. ~~However~~, **but we cannot guarantee applicable insurance will be available to us in the future on economically reasonable terms or at all.** ~~damages~~ **Damages** and claims arising from ~~specific~~ incidents may not be covered, may exceed the amount of any coverage **limits**, and ~~do may~~ not cover the time and effort we incur investigating and responding to any incidents, **or other costs or liabilities**, which may be material. The costs to eliminate, mitigate, ~~or~~ recover from security problems and cybersecurity attacks and incidents could be material and **require us to implement additional or different security controls or other measures and**, depending on the nature and extent of the problem and the ~~networks or~~ products, ~~services or~~ IT systems impacted, **such security problems and cybersecurity attacks and incidents** may result in network ~~or~~, ~~IT systems~~ ~~system~~ interruptions **or other disruptions**, decreased product sales, ~~or~~ data loss ~~that~~, **damage, unavailability, or other liabilities, any of which** may have a material impact on our operations, net revenues and operating results. Additionally, our iTero ~~intraoral~~ scanners ~~sold~~ may be independently or collectively the target of cybersecurity incidents or attacks or subject to security vulnerabilities, bugs, errors, defects, or viruses or other malicious code. Due to the large and growing number of these decentralized devices, we may be unable, or not have the capacity, knowledge or infrastructure, to respond to or remedy a cybersecurity incident in a timely manner. Any such cybersecurity incident may cause loss or **damage to us, our** customers ~~or~~ globally, strategic business partners or other locations may be independently or collectively the target of cybersecurity incidents or attacks or subject to viruses, bugs, or other similar negative intruders. Due to the large and growing number of these decentralized devices, we may be unable, or not have the capacity, knowledge, or infrastructure, to respond to or remedy a cybersecurity issue in a timely manner, which may cause loss or damage to us, our customers, or

strategic business partners or may cause further malfunctions in, or damage to, our **products, servers, services, databases, or IT systems or products and services, damage to, or loss, unavailability, or damage- unauthorized acquisition, use, or other processing** of our data, **or disruption**, interruption or temporary cessation of our operations. Further, **or an any overall such security breach or incident, or other cybersecurity incident, or any belief or reporting that any of the foregoing has occurred, may otherwise have a** negative impact **to upon** our business or reputation. We are also subject to federal, state, and foreign laws and regulations respecting the security and privacy of patient healthcare information applicable to healthcare providers and their business associates, such as ~~HIPAA~~ **HIPPA, the HITECH Act, and the Privacy Standards and Security Standards**, as well as those relating to privacy, data security, content regulation, and consumer protection, such as **the California Consumer Protection Act, as amended by the California Privacy Rights Act (as amended, the "CCPA")**. ~~We~~ **The CCPA requires covered businesses that process personal information of California residents to disclose certain practices, provides California residents with data privacy rights, imposes operational requirements, and provides for significant civil penalties for violations as well as a private right of action for certain data breaches and statutory damages. There are limited exemptions under the CCPA for protected health information covered by HIPAA and certain other state laws, but the CCPA and other new and evolving state laws could impact our business activities. Numerous other states have enacted laws relating to privacy, data protection, data governance and cybersecurity that either are in operation or slated to go into operation over the next several years. Many of these laws are comprehensive privacy laws similar to the CCPA. States also are enacting laws addressing specific subject matter, such as Washington's My Health, My Data Act, which includes a private right of action. Laws in all 50 U. S. states may require businesses to various national and regional provide notice to individuals whose personal data localization or has been disclosed as a result of a data residency laws, including breach. Outside of the U. S. state law, relevant legal requirements continue to evolve. For example, the collection and use of health data and other personal information is governed in the EU by the General Data Protection Regulation ("GDPR"), which imposes significant obligations upon companies and analogous rights for individuals, with substantial penalties for noncompliance up to the greater of € 20, 000, 000 or 4 % of the total worldwide annual turnover of the preceding financial year, and by certain EU member state- level legislation. Numerous other jurisdictions maintain similar legislation or other laws in or regulations addressing privacy, data protection, data governance, or cybersecurity. We are also subject to data export restrictions and international transfer laws and regulations that prohibit or impose conditions upon certain data transfers. The mechanisms upon which we and many other companies rely upon for European data transfers have been the subject of legal challenge, regulatory interpretation and judicial decisions by the EU courts and regulators, and may be subject to significant changes. Several countries, including the United States, China which generally require, Australia, and Japan, have established legal requirements for cross- border transfers of all or certain personal information types of data collected within a country be stored and certain processed only within that country or approved countries. Other countries are considering similar have also established legal requirements for data localization. These laws and regulations are constantly evolving and may be created, interpreted, applied or amended in ways that could restrict or our activities in certain jurisdictions, limit our ability to provide our products and services in those jurisdictions, require us to modify our policies and practices and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data residency laws across borders. We have and likely will again in the future be required to implement new or expand existing data storage protocols, build new storage facilities, and/ or devote additional resources, and modify relevant policies or procedures to comply with such the foregoing laws, any of which could be costly.** ~~We are also subject to data export restrictions and international transfer laws which prohibit or impose conditions upon the transfer of such data. These laws and regulations are constantly evolving and may be created, interpreted, applied, or amended in ways that adversely affect our business and our customers' businesses, our financial condition and our results of operations in those jurisdictions. With laws, regulations and other obligations relating to privacy, data protection, data governance and cybersecurity imposing new and relatively burdensome obligations, and with substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. Further, any failure or perceived failure by us or our vendors, customers, or service providers to comply with our applicable policies or notices relating to privacy, data protection, data governance or cybersecurity, our contractual or other obligations to third parties, or any of our other legal obligations, laws, rules, regulations or standards relating to privacy, data protection, data governance or cybersecurity, may result in governmental investigations or enforcement actions, litigation, claims and other proceedings, harm our reputation, and could result in significant liability.~~ Our business exposes us to potential liability for the quality and safety of our products and services, how we advertise and market those products and services, and how and to whom we sell them, and we may incur substantial expenses or be found liable for substantial damages or penalties if we are subject to claims or litigation. Our products and services involve an inherent risk of claims concerning their design, materials, manufacture, safety, and performance, how they are marketed and advertised in a complex framework of highly regulated domestic and international laws and regulations, how we package, bundle, or sell them to individual customers or companies, including hospitals and clinics, and how we train and support doctors, their staffs and patients who use our products **and services**. Moreover, consumer products and services are routinely subject to claims of false, deceptive or misleading advertising, consumer fraud and unfair business practices. Additionally, we may be held liable if our products or services cause injury or are otherwise found unhealthy. If our products **and services** are safe but they are promoted for use or used in unintended or unexpected ways or for which we have not obtained clearance (" off- label " usage), we may be investigated, fined or have our products or services enjoined or approvals rescinded or we may be required to defend ourselves in litigation. Although we maintain insurance for product liability, business practices, and other types of activities we make or

offer, coverage may not be available on acceptable terms, if at all, and may be insufficient for actual liabilities. Any claim for product liability, sales, advertising and business practices, regardless of its merit or eventual outcome, could result in material legal defense costs and damage our reputation, increase our expenses, and divert management's attention. **Increased focus on current Current** and anticipated **environmental, sustainability and social and governance** (" **ESG Sustainability** ") laws and scrutiny of our **ESG Sustainability** policies and practices may materially increase our costs, expose us to liability, and adversely impact our reputation, employee retention, willingness of customers and suppliers to do business with us and willingness of investors to invest in us. Our operations are subject to a variety of existing local, regional and global **ESG Sustainability** laws and regulations, and we are and may be required to comply with new, broader, more complex and more costly **ESG Sustainability** laws and regulations, **such as the EU's Corporate Sustainability Reporting Directive**. Our compliance obligations span all aspects of our business and operations, including product design and development, materials sourcing and other procurement activities, product packaging, product safety, energy and natural resources usage, facilities design and utilization, recycling and collection, transportation, disposal activities and workers' rights. **Environmental Sustainability** regulations **related to greenhouse gases, hazardous materials, sustainability and reduction of waste** are expected to have an increasingly larger impact on us or our suppliers. Many U. S. and foreign regulators have or are considering enacting new or additional disclosure requirements or limits on the emissions of greenhouse gases, **including carbon dioxide and methane**, from power generated using fossil fuels. The effects of greenhouse gas emission limits on power generation are subject to significant uncertainties, including the timing of new requirements, levels of emissions reductions and the scope and types of emissions regulated. Additionally, **as Sustainability** laws on **sustainability and waste reduction** are increasing, **customers** and consumers may demand our products, packaging and operations be more sustainable, affect how we manufacture and package our products, increase our costs and those of our suppliers, and **which** may result in manufacturing, transportation and supply chain disruptions if **sustainable** clean energy **is or sustainable alternatives are** not readily available in adequate amounts when required. Moreover, **alternative** clean energy sources, coupled with reduced investments in traditional energy production and infrastructure, may not provide the predictable, reliable, and consistent energy **that** we, our suppliers and other **businesses-- business partners** require. Additionally, the sourcing and availability of metals used in the manufacture of, or contained in, our products may be affected by laws and regulations governing the use of minerals obtained from certain regions of the world like the Democratic Republic of Congo and adjoining countries. **Our** ~~Although we do not believe we source minerals from this region, our~~ expanding geographic operations may increase the risk of purchasing " conflict minerals " and our **diligence** efforts to identify whether any of our products contain minerals impacted by these laws and regulations may not be **accurate**, adequate or complete. Other restrictions apply to the substances incorporated into our products, including the chemical compounds in our clear aligners, the electronics in our iTero **intraoral** scanners, and the packaging in which they are shipped. These laws are proliferating and new substances subject to restrictions are **added** regularly **being added each year and may require additional reporting or phasing out of certain chemicals and compounds such as per- and polyfluoroalkyl substances (PFAS)**. We may be **forced required** to re- design our products or identify new suppliers to maintain our compliance with these laws. Further, these laws and regulations may decrease the number of suppliers capable of supplying our needs, thereby negatively affecting our ability to manufacture products in sufficient quantities at competitive prices, leading customers to potentially choose competitive goods and services. Meeting our obligations under existing **ESG Sustainability** laws and regulations is costly for us and our suppliers, and we expect these regulations and costs to increase **materially, in particular as the regulatory frameworks in each jurisdiction in which we operate become more complex and distinct**. Additionally, regulators may perform investigations, inspections and periodically audit our compliance with these laws and regulations, and ~~we cannot be sure~~ our efforts or operations **will may not** be compliant. If we fail to comply with any requirements, we could be subject to significant penalties or liabilities and we may be required to implement new and materially more costly processes and procedures. Even if we successfully comply with these laws and regulations, our suppliers may not. We may also suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are **complaint-compliant**. In all of these situations, customers may stop purchasing products from us, and may take legal action against us, which could harm our reputation, ~~revenues~~ **business, financial condition** and results of operations. Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and customers **are also increasingly have and could in the future** ~~focused~~ **focus** on corporate **ESG Sustainability** practices. Additionally, public interest and legislative pressure related to companies' **ESG Sustainability** practices **has been** continues to grow. ~~If our ESG practices fail to meet investor or other industry stakeholders' frequently evolving expectations and standards, our brand, reputation and employee retention may be harmed, customers and suppliers may be unwilling to do business with us and investors may be unwilling to invest in us recent years~~. If we fail to adopt **ESG Sustainability** standards or practices as quickly as stakeholders desire, comply with or timely report on our **ESG Sustainability** efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our **brand, reputation, employee retention**, business, financial performance, growth, and stock price may be adversely impacted. We have been incorporating and continue to work to further incorporate **artificial intelligence (" AI technologies ")** into our products, services and **IT systems internal operations**. Implementation of AI and machine learning technologies may result in legal and regulatory risks, reputational harm or have other adverse consequences to our business. We have and are continuing to incorporate AI, including machine learning and independent algorithms, in certain of our products, services and **IT systems internal operations**, which is intended to enhance their operation and effectiveness internally and for our customers, **suppliers and** consumers and suppliers. ~~There can be no assurance that we or our customers will realize the expected benefits from these investments~~. AI innovation presents risks and challenges that could impact our business. Our, ~~our~~ vendors', AI algorithms may be flawed. Our datasets or AI training algorithms may be insufficient or contain biased information. Additionally, many countries and regions, including the EU, have proposed new and evolving regulations related to the use of AI and machine learning technologies. **In Europe, the EU The regulations may impose onerous obligations and**

may require us to unexpectedly rework or reevaluate improvements to be compliant. Use of AI Act entered into force on August 1 technologies may expose us to an increased risk of regulatory enforcement and litigation. Moreover, 2024 which will become fully effective on August 2, 2026, with some of provisions effective in February 2025. Other -- the jurisdictions are considering similarly focused legislation. AI features involve the processing of personal data and may be subject to laws, policies, legal obligations, and codes of conduct related to privacy and data protection. AI Although we do not engage in developing development and deployment or providing AI systems for which their placement on the market, putting into service, or use would qualify as "prohibited AI practices" could subject us to competitive harm, "restrictions and obligations under this regulation -- regulatory enforcement, increased cybersecurity risks, reputational harm and legal liability".

Intellectual Property Risks Our success depends in part on our proprietary technology, and if we fail to successfully obtain or enforce our IP rights, our competitive position may be harmed. Our success depends in part on our ability to maintain existing IP rights and obtain, maintain and enforce further IP protections for our products. Our inability to do so could harm our competitive position. We rely on our portfolio of issued and pending patent applications in the United States U. S. and other countries to protect a large part of our IP and our competitive position; however, these patents may not prevent third parties from producing competing products similar in design to ours if they are invalidated, held unenforceable, circumvented, or otherwise limited in scope. Furthermore, our foreign patent protections may be more limited in geographic scope than those under U. S. patent and IP laws. Additionally, any of our patent applications may not result in an issued patent or the scope of the patent ultimately issued may be narrower than initially sought. We may not be afforded the protection of a patent if our currently pending or future patent filings do not result in the issuance of patents or we fail to timely apply for patent protection. We may not apply for a patent if our personnel fail to disclose or recognize new patentable ideas or innovations. Remote working can decrease opportunities for our personnel to collaborate, thereby reducing invention disclosures and patent application filings. We may choose not to file a foreign patent application if the limited protections provided by a foreign patent do not outweigh the costs to obtain it. Further, third parties may file patents or develop IP strategies that prevent or limit the effectiveness of our patents. We also protect our IP through copyrights, trademarks, trade secrets, and confidentiality obligations. We generally enter into confidentiality agreements with our employees, consultants and collaborative partners upon commencement of a relationship with us. However, despite the existence of these protections, we have experienced incidents in which our proprietary information has been misappropriated and believe it will could be misappropriated again in the future. If these agreements do not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, adequate remedies may not exist to prevent unauthorized uses or disclosures. Enforcement of our IP rights is time-consuming and costly, and could ultimately prove to be unsuccessful. In certain jurisdictions, enforcement of IP rights is more difficult due to legislation and geopolitical circumstances. As we launch our products in different regions at different times, our products may be acquired and reverse engineered by potential competitors in regions where infringement is more difficult to pursue. Our inability to maintain the proprietary nature of our technology through patents, copyrights, or trade secrets would impair our competitive advantages and could have a material effect on our operating results, financial condition, and future growth prospects. In particular, a failure to protect our IP rights might allow competitors to copy our technology or create counterfeit or pirated versions of our products, which could adversely affect our reputation, pricing, and market share. Litigation regarding our IP rights, rights claimed by third parties, or IP litigation by any vendors on whose products or services we rely for our products and services may impact our ability to grow our business, and adversely impact our reputation and results of operations and adversely impact our reputation. Extensive litigation over IP rights is common in technologies and industries on which our products and services are based. Litigation, interferences, oppositions, re-exams, inter partes reviews, post grant reviews or other proceedings have been necessary and will likely be needed in the future to determine the validity and scope of certain of our IP rights and those claimed by third parties. These proceedings are used to determine the validity, scope or non-infringement of certain patent rights pertinent to the manufacture, use or sale of our products and the products of competitors. We have been sued for infringement of third parties' patents in the past and are currently defending patent infringement lawsuits and other legal claims. In addition, we periodically receive letters from third parties drawing our attention to their IP rights and there may be other third-party IP rights of which we are presently unaware. As dentistry continues to become more digital, competitors may make defense of our IP more challenging. Asserting or defending these proceedings can be unpredictable, protracted, time-consuming, expensive, and distracting to management and technical personnel. Their outcomes may adversely affect our ability to manufacture and market our products and services, require us to seek licenses for infringing products or technologies, or result in the assessment of significant monetary damages. Unfavorable rulings could include monetary damages, injunctions prohibiting us from selling our products, or exclusion orders preventing us from importing our products in one or more countries. Moreover, independent actions by competitors, customers, or others have alleged that our efforts to enforce our IP rights constitute unfair competition or violations of antitrust laws and investigations and additional litigation based on the same or similar claims may be brought in the future. The potential effects on our business operations resulting from litigation, whether or not ultimately determined in our favor or settled by us, are costly and could materially affect our reputation, business, financial condition and results of operations and reputation. Financial, Tax and Accounting Risks If our goodwill, intangible or long-lived assets become impaired, we may be required to record a material charge-charges to earnings income. Under U. S. GAAP, we review our goodwill at least annually and, or more frequently, if we identify events or circumstances that indicate it is more likely than not that the fair value of a reporting unit has been reduced below its carrying value. We review finite-lived intangible assets and long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the asset (asset group) may not be recoverable. The qualitative analysis performed by management to identify indicators of impairment or the quantitative analysis used to determine fair value requires management to exercise significant judgement in determining appropriate assumptions and estimates, including revenue growth rates, gross and operating margins, and discount rates and future cash flows. Management is responsible for continually assessing

qualitative factors that could negatively impact the fair value of goodwill and intangible and long-lived assets and if required, assesses the fair value of each to determine if they have become impaired. Consequently, we may be required to record a material **charge charges** to earnings **on** our financial statements during the period in which any impairment of goodwill, intangible **assets** or long-lived **asset-assets group** is determined. Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges. We prepare our consolidated financial statements in conformity with **U. S.** GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting **policies-principles**. A change in these **policies-principles** or in the way these **policies-principles** are interpreted by us or **by our** regulators could materially **effect our reported results and may even retroactively affect our current or previously reported-issued** financial statements. We are required to annually assess our internal control over financial reporting and any adverse results from such assessment may result in a loss of investor confidence in our financial reports and adversely affect our stock price. We are required to furnish in our **Annual Report on** Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting that includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including **a statement an assertion by management that our internal control over financial reporting were effective** as to whether it is effective **of the end of our fiscal year**. Our internal controls may become **inadequate-ineffective** because of changes in personnel, updates and upgrades to or migration away from existing software, failure to maintain accurate books and records, changes in accounting standards or interpretations of existing standards, **or changes to business models that may require adjustments to our financial reporting** and, as a result, the degree of compliance of our internal control over financial reporting with the existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, **and** may require additional staffing and infrastructure investments and increases our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective, **in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls, or conclude that our internal controls are ineffective),** the timely filing of our financial reports could be delayed or we could be required to restate past reports, **and, This could** cause **us our investors** to lose **investor** confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price. **If we fail to manage our exposure to global financial and securities market risks successfully, our operating results and financial statements could be materially impacted.** A majority of our marketable investments are investment grade, liquid, fixed-income securities and money market instruments denominated in U. S. dollars. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U. S. financial sector. In an unstable credit or economic environment, it is necessary to assess the value of our investments more frequently and we might incur material realized, unrealized or impairment losses associated with these investments. Additionally, bank failures could cause or continue to cause volatility in the credit or capital markets, market-wide liquidity issues, bank runs and general concern across the global financial industry. These conditions could limit our access to capital or impair the value of assets we hold. Our effective tax rate may vary significantly from period to period, **which could result in volatility of our operating results and adversely affect our financial results**. We are subject to taxes in the **United States** U. S. and foreign countries. Various internal and external factors may **affect impact** our future effective tax rate. These **factors** include changes in the global economic environment, our legal entity structure or activities performed within our entities, our business operations, **in** tax laws, regulations and / or rates, **changes** to existing accounting pronouncements, **changes in** interpretations of existing tax laws or regulations, **in the** relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, **in** overall levels of pretax earnings, **as well as the settlement settlements** of income tax audits **and,** non-deductible goodwill impairments, **and changes in the valuation allowance offsetting deferred tax assets**. Furthermore, we may continue to experience variation in our effective tax rate related to excess tax benefits or tax expense on stock-based compensation, particularly in the first quarter of each year when the majority of our equity awards vest. New tax laws and practices, changes to existing tax laws and practices, or disputes regarding the positions we take regarding tax laws, could negatively affect our provision for income taxes as well as our ongoing operations. Compliance with tax laws requires significant judgment concerning our worldwide provision for income taxes. Changes in tax laws or changes to how those laws are applied to our business could affect the amount of tax which we are subject to and the manner in which we operate. Specifically, **in 2016,** the Organization for Economic Cooperation and Development (“OECD”) established the Inclusive Framework on Base Erosion and Profit Shifting (“BEPS”) to among other things, allocate greater taxing rights to countries where customers are located and establish a global minimum tax rate. **Countries including EU member** After years of evaluating their respective tax laws, many countries have enacted **changes, or are considering** committed to enacting **changes, which may increase our tax expense in future years.** For example, the European Union and other countries have enacted **or have committed to enact the OECD / G20 Framework’s Pillar Two 15 % global minimum tax, including Switzerland which is a significant jurisdiction for us.** **If more countries adopt We continue to monitor these-- the changes based on enactment of legislation to evaluate the BEPS guidance impact of changing global tax laws, which could adversely affect** our provision for income taxes or operations **may be adversely affected.** Moreover, the application of indirect taxes (such as sales and use tax (“SUT”), value-added tax (“VAT”), goods and services tax (“GST”), and other indirect taxes) to our operations is complex and evolving. U. S. states, local and foreign taxing jurisdictions have differing rules and regulations governing differing types of taxes, and these rules and regulations are subject to varying interpretations and exemptions that may change over time. We collect and remit SUT, VAT, GST and other taxes in many jurisdictions and we are routinely subject to audits. **We are also routinely audited regarding our tax reporting and remissions by local and national governments, and may also be subject to**

audits in jurisdictions for which we have not accrued tax liabilities. The positions we take regarding taxes as well as the amounts we collect or remit **have and may continue to** be challenged and we may be liable for failing to collect or remit all taxes deemed owed or the taxes could exceed our estimates. **We** One or more U. S. states or countries may seek to impose incremental or new sales, use, or other tax collection obligations or may determine that such taxes should **have and may continue to** but have not been paid by us. If we dispute rulings or positions taken by tax authorities, **we which have and may continue to** incur significant expenses, time, and effort to defend our positions. During the year ended December 31, 2023, the Company received a notice and initial assessment from His Majesty's Revenue and Customs ("HMRC") for unpaid VAT related to certain clear aligner sales made during various periods beginning 2019 through 2023. While we assert that these sales are exempt from VAT, that we have reasonably relied upon statements and guidance by HMRC and that our interpretation of relevant legislation is appropriate, and believe that a potential loss related to unpaid VAT is not probable, it is possible that we may be subject to a loss in connection with unpaid VAT. The application of existing and new tax laws, and the results of audits could harm our business. Furthermore, there have been and will continue to be substantial ongoing costs associated with complying with the various tax requirements and defending our positions in the numerous markets in which we conduct or will conduct business. Historically, the market price for our common stock has been volatile. The market price of our common stock is subject to rapid and large price fluctuations attributable to various factors, many of which are beyond our control. The factors include: • quarterly variations in our results of operations and liquidity, **our ability to meet or exceed our forecasts and guidance** or changes **in to our or withdrawal of our previous** forecasts and guidance; • our ability to regain or sustain our historical growth rates; • changes in recommendations **or valuation models for our stock** by the investment community, or speculation in the press or investment community regarding estimates of our net revenues, **operating results of operations**, or other **key** performance indicators; • announcements by us **or**, our competitors, or new market entrants, including strategic actions, management changes, and material transactions or acquisitions; • technical factors in the public trading markets for our stock that may produce price movements inconsistent with **macro-macroeconomic**, industry, or company-specific fundamentals, including the sentiment of retail investors (as it may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock, fractional share trading, and other technical trading factors or strategies; • **stockholder activism or securities class action litigation**; • announcements regarding stock repurchases, sales or purchases of our common stock by us, our officers or directors, credit agreements, and debt issuances; • announcements of technological innovations, **or** new, additional or revised programs, business models, products, or product offerings by us, our customers, or competitors; • key decisions in pending litigation, new litigation, settlements, judgments, or decrees; • **short selling or other hedging activity in our stock**; and • general economic market conditions, including rising interest rates, **tariffs**, inflationary pressures, recessions, consumer sentiment and demand, global **political-geopolitical** conflict, and industry factors unrelated to our actual performance. In addition, the stock market in general, and the market for technology and medical device companies, in particular, often experience extreme price and volume fluctuations unrelated or disproportionate to corporate operating performance. **Any such fluctuations have and may continue to adversely affect the market price of our common stock**. These broad market and industry factors may include market expectations of, or actual changes in, monetary policies that have the goal of easing or tightening interest rates such as the U. S. federal funds rate and austerity measures of governments intended to control budget deficits. Securities litigation, including securities class action lawsuits and securities derivative lawsuits, is often brought against an issuer following periods of volatility in the market price of its securities and we have not been exempt from such litigation. We cannot guarantee that we will continue to repurchase our common stock in the future, and any repurchases we may make may not achieve our desired objectives. We have a history of recurring stock repurchase programs intended to return capital to our investors. Future stock repurchase programs are contingent on a variety of factors, including our financial condition, market conditions, results of operations, business requirements, and our continuing determination that stock repurchases are in the best interests of our stockholders and in compliance with all applicable laws and agreements. There is no assurance that we will continue repurchasing our common stock in the future at historical levels or at all, or that our stock repurchase programs will beneficially impact our stock price. Additionally, effective January 1, 2023, the Inflation Reduction Act imposes a 1 % excise tax on our stock repurchases, **net of certain stock issuances**, which will increase our tax liabilities and the cost to **retire repurchase** stock and may impact if and how much stock we choose to repurchase in the future. Future sales of significant amounts of our common stock may depress our stock price. A significant percentage of our outstanding common stock is currently owned by a small number of stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of our stock over relatively short periods of time. Sales of substantial amounts of our stock by existing stockholders may adversely affect the market price of our stock by creating the perception of difficulties or problems with our business **that, which** may depress our stock price. 34