

Risk Factors Comparison 2024-02-28 to 2023-02-27 Form: 10-K

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

The **Company's** following discusses some of the risks that may affect our business, **reputation**, results of operations and financial condition **and stock price can be affected by a number of factors, whether currently known or unknown, including those described below.** ~~You~~ **When any one or more of these risks materialize from time to time, the Company's business, reputation, results of operations, financial condition 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 the Company's results of operations and financial condition, past financial performance should carefully 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** ~~The order we have chosen to list the risks below or the sections in which we have identified them should~~ **consider** ~~not be interpreted to mean we deem any risks to be more or less important or likely to occur or, if any do occur, that their impact may be any less significant than others. These~~ **these** risk factors should be considered in connection with evaluating the forward-looking statements contained in this report ~~because they could cause our actual results and conditions to differ materially from those statements. Before you invest in Align, you should know that investing involves risks, including those described below. The risks below are not the only ones we face. If any of the risks actually occur, our business, financial condition and results of operations could be negatively affected, the trading price of our common stock could decline, and you may lose all or part of your investment.~~ Summary of Risk Factors Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows, and prospects. These risks are discussed more fully below and include, but are not limited to: ~~Macroeconomic and External Risks • Global and regional economic conditions • Major health crises • Political events, international disputes, war and terrorism • Natural disasters Business and Industry Risks • Changes in demand for our products • Increased competition • Failure of our new products, or changes to our existing products, to attract or retain consumers or generate revenue • Our ability to successfully integrate our acquisitions Operational Risks • Business disruptions • Predicting demand • Availability of supplies • Shipping delays • Personnel development and retention • Effectiveness of marketing and our ability to attract consumers Legal, Regulatory and Compliance Risks • Government investigations, enforcement actions, and settlements • Our ability to comply with laws and regulatory and legislative mandates or guidance • Privacy, cybersecurity and data protection • Litigation, including class action lawsuits Intellectual Property Risks • Our ability to obtain, maintain, protect, and enforce our intellectual property rights Financial, Tax and Accounting Risks • Impairment of our goodwill • Compliance with accounting, financial reporting, and tax laws • Management of our stock plans • Volatility of our stock~~ Our operations and financial performance depend on global and regional economic conditions. Inflation, fluctuations in currency exchange rates, changes in consumer confidence and demand, and ~~weakness in~~ **weakness** ~~in~~ general economic conditions ~~and~~ **weakness** and threats, or actual recessions, have and could in the future materially affect our business, results of operations, and financial condition. 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 currency exchange rates, ~~weakness in~~ **weakness** ~~in~~ general economic conditions ~~and~~ **weakness**, threats or actual recessions, pandemics, wars and military actions, ~~employment~~ **employment** levels of ~~employment~~, wages, debt obligations, discretionary income, interest rates, volatility in capital, and consumer confidence and perceptions of current and future economic conditions. **Macroeconomic conditions** ~~Changes and uncertainty~~ can, among other things, reduce or shift spending away from elective treatments and procedures, drive patients to ~~purchase~~ **pursue less costly** orthodontic treatments ~~that may cost less than our Invisalign treatment options, result in a decrease in the number of overall orthodontic and dental 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~~ ~~recent~~ declines in, or uncertain economic outlooks for, the U. S., Chinese, European and certain other international economies ~~has~~ **have** and may continue to adversely affect consumer and dental practice spending. ~~The increase~~ **Increases** in the cost of fuel and energy, food and other essential items ~~along with climbing as well as higher~~ interest rates ~~could have and may continue to~~ reduce consumers' disposable income, ~~resulting which could cause a decrease in less~~ discretionary spending for products like ours. ~~Decreases~~ **Further, we cannot predict the impact of efforts by central banks and federal, state and local governments to combat inflation, which could result in disposable income and an** ~~discretionary~~ **economic recession or have an adverse impact on consumer** spending ~~may or for a prolonged period of time~~ change in consumer confidence and spending habits has and may continue to adversely affect our revenues and operating results. Inflation continues to adversely impact spending and trade activities, ~~causing unpredictable~~ **causing unpredictable** and we are unable to predict the impacts of ~~higher inflation~~ on global and regional economies. Higher inflation has also increased domestic and international shipping costs, raw material prices, and labor rates, which ~~could~~ **has** adversely ~~impact~~ **impacted** the costs of producing, procuring and shipping our products. Our ability to recover these cost increases through price increases may continue to lag, 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. ~~Further, we are unable to predict the impact of efforts by central banks and federal, state and local governments to combat elevated levels of inflation. If their efforts to reduce inflation~~

are too aggressive, they may lead to a recession. Alternatively, if they are insufficient or are not sustained long enough to lower inflation to more acceptable levels, consumer spending may be adversely impacted for a prolonged period of time. Any of these events could materially affect our business and operating results. We have **significant** international operations and sales outside and we are exposed to fluctuations in foreign currencies that have adversely impacted our business or results of operations. Although the U. S. dollar is our reporting currency, a large portion of our total revenues from international sales generated through our foreign direct and indirect operations and we expect to increase our sales and presence outside the U. S., particularly in markets we believe have high growth potential. Moreover, we perform most of our key production steps in locations outside of the U. S. For instance, we perform our digital treatment planning and aligner fabrication in multiple international locations, including large-scale operations in Mexico, Costa Rica, Poland, Japan and China. Additionally, we maintain significant global sales and marketing operations in Switzerland, Singapore and China, along with research and development operations globally, including in the U. S., Spain, Israel, Armenia and Germany. Our reliance on international operations and sales exposes us to fluctuations in foreign currencies that may adversely impact our business or results of operations. Although the U. S. dollar is our reporting currency, a growing portion of our net revenues and net income are generated in foreign currencies. While we utilize forward contracts to reduce moderate the adverse earnings impact from the effect of exchange rate fluctuations on certain assets and liabilities, our hedging strategies may not be successful, and currency exchange rate fluctuations have and could may continue to have a material materially adverse adversely effect on our operating results 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 continue to have a material materially impact on our financial results in periods when the U. S. dollar significantly fluctuates in relation to foreign currencies. Our business could be impacted by geopolitical events, trade and other international disputes, war, and terrorism, or major public health issues crises. Political events, trade including pandemics, and other international disputes, war and terrorism, our or business has been and continues to be materially affected by the global and regional spread of COVID-19. Major major public health crises issues, including pandemics such as the spread of COVID-19, have adversely affected, and could in the future harm materially affect, our or disrupt international commerce and business due to their impact on the global economy and could materially regional economies, demand for consumer products, the imposition or removal of public safety measures. Public health concerns may also limit the movement of products between regions, disrupt or delay supply chains and sales and distribution channels, resulting in interruptions of the supply of products. While we maintain insurance coverage for certain types of losses, such insurance coverage may be insufficient to cover all losses that may arise. COVID-19 has created significant, widespread and unprecedented volatility, uncertainty, and economic instability, disrupting broad aspects of global and regional economies, our operations and the businesses of our customers and suppliers. Many of these effects effect continue to varying degree as variants of COVID-19 and outbreaks globally or regionally continue to harm recovering consumer confidence. Therefore, comparing our financial results for the reporting periods of 2022 to the same reporting periods of 2021 or earlier may not be a useful means by which to evaluate the health of our business and our results of operations. As a result of outbreaks of COVID-19 and its variants, customer demand and doctor availability has been inconsistent and difficult to predict. Although the practices of the doctors, dental service organizations and labs that are our principal customers have largely reopened following the initial outbreak of COVID-19 in 2020, many continue to operate at less than pre-pandemic capacities. For example, in China the impact of widespread population lockdowns under the country's zero tolerance policies was more pronounced in 2022, leading to the complete closure of dental offices in major metropolitan and other areas for extended periods of time. Conversely, the reversal of China's zero tolerance policies has resulted in a significant increase in infections that may impact consumer and doctor demand in 2023. These fluctuations are currently and have previously adversely impacted our results of operations and are expected to continue to impact our results, particularly in the near term. The effects of the pandemic continue to linger and evolve and we cannot predict future direct and ancillary impacts on our business or results of operations, although they may be material to our business as well as the businesses of our customers, suppliers and economic activity generally. The COVID-19 pandemic has impacted virtually all aspects of our business and society. It has exacerbated many pre-existing risks to our business by making them more likely to occur or more impactful when they do occur. Accordingly, you should consider the risks described in this risk factor in addition to, and not in lieu of, the risks described elsewhere throughout these risk factors. Our business could be impacted by political events, trade and other international disputes, war, and terrorism, including the military conflict between Russia and Ukraine. Political events, trade and other international disputes, war, and terrorism could harm or disrupt international commerce and the global economy and could have a material effect on our business as well as our customers, suppliers, contract manufacturers, distributors, and other business partners. Political events, Such risks include supply chain and trade disruptions and other international disputes, wars, and terrorism can lead to unexpected tariffs or, trade sanctions or restrictions, which could boycotts, reduced consumer spending, government shut downs, or cyberattacks, energy shortages or power outages, energy rationing that adversely impact impacts our manufacturing facilities, rising fuel our or business 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, telecommunications failures or destruction of property. Tariffs, such as those on Chinese goods, and responses to the tariffs may increase the cost of our products and the components and raw materials used to make them. These increased Increased costs could adversely impact our gross margin and make our products less competitive or reduce demand for our products. Countries could may also adopt other measures, such as controls on the imports import or exports export of goods, technology or data, that could would adversely impact our operations and supply chain chains and or limit our ability to offer products and services. These measures could require us to take various actions, including changing suppliers or restructuring business relationships. Complying with new or changed trade restrictions is expensive, time-consuming and disruptive to our operations. Such restrictions can be announced with little or no advance notice

and we may be unable to effectively mitigate the **any** adverse impacts of such measures. If **Political events, trade and other international** disputes and conflicts escalate in the future, **war** actions by governments in response could be significantly more severe and restrictive and could materially affect our business. Political unrest, threats, tensions, actions and responses to any social, economic, business, geopolitical, military, terrorism, or acts of war **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 **operation operations**. For example **The impact to us**, our employees in Israel **and customers** could **would** be obligated to perform annual reserve duty in the Israeli military and be called for additional active duty under emergency circumstances. If any of these events or conditions occur, the impact to us, our employees and customers is uncertain, particularly if emergency circumstances, armed conflicts or an escalation in political instability or violence, **or viral out- breaks** ~~disrupts~~ **disrupt** our product development, data or information exchange, payroll or banking operations, product or materials shipping by us or our suppliers **and**. **Our internation 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. ~~The military~~ **Military** conflict **conflicts** between Russia and Ukraine has **global pandemics have** materially adversely impacted **our** global economies, and has materially impacted our global and regional operations. **For example** Governments including the U. S., **our** United Kingdom, and those of the European Union have imposed export controls on certain products and financial and economic sanctions on certain industry sectors and parties in Russia which has triggered retaliatory sanctions by the Russian government and its allies. **Our commercial operations in Russia were impacted by the conflict in Ukraine and we were affected by the COVID- 19 pandemic. Our iTero operations, headquartered in Israel, are close to areas that** have been impacted ~~affected~~ **by the conflict ongoing violence** and if we fail to support existing customers, we may frustrate those customers, harm our reputation, and be subject to regulatory action in Russia. Additionally, a majority of our research and development personnel in Russia relocated to locations outside of Russia in 2022. Whether they remain in their new locations over the long- term remains unknown. If we are unable to retain key skilled personnel from where they have relocated, or we are unable to quickly replace such personnel with individuals of equivalent technical expertise and qualifications, our business and financial condition could be materially effected. The outcome and future impacts of the Russia and Ukraine conflict remain highly uncertain, continue to evolve and may grow more severe the longer the military action and sanctions remain in effect. Moreover, **the Middle East and this may impact our employees as well as our iTero business. Some employees and consultants in Israel have been called for military service in the current** conflict **in the Middle East** and existing and future sanctions may have broad and pervasive impacts to the **they** global and regional economies and our operations, heightening and affecting many ~~may be absent for~~ of the other risks described elsewhere throughout these risk factors, any ~~an unknown period~~ of time. Furthermore, **our facility may be damaged or supply chains impaired as a result of hostilities** which could **disrupt ongoing operations and impact our financial results. The conflict in the Middle East may** materially and adversely affect our business and results of operations. Such risks include adverse effects on general economic and political conditions such as inflation, supply chain and trade disruptions, and reduced consumer spending; disruptions to our IT systems, including through network failures, malicious or disruptive software, or cyberattacks; energy shortages or rationing that may adversely impact **the timing** our manufacturing facilities; rising fuel and /or rising costs ~~cost~~ of producing, procuring and shipping of our products ; our exposure to foreign currency exchange rate fluctuations; and constraints, volatility or **our ability to operate out of Israel**, disruption in the financial markets. We may not be successful in our ~~or~~ efforts **lead** to mitigate the negative impacts of the conflict, particularly the longer sanctions and retaliatory sanctions remain in effect. How we respond to the conflict may also subject us to risk. The resumption of sales in Russia or our decision to continue supporting our personnel and existing customers in Russia may result in reputational harm or boycotts **which** of our products that could impact our sales and **revenues. Additionally, the recent election in Taiwan and China's territorial conflicts with other neighboring countries may impact our operations inside and sales** outside of Russia or subject us to litigation for which we may be found liable in **China** courts or other tribunals in Russia or elsewhere. Moreover, production could be impaired should hostilities spread to other countries such as Poland, where our newest aligner fabrication facility is located. We ~~cannot have no way to~~ predict the progress or outcome of the ~~these events~~ conflict in Ukraine or the reactions by governments, businesses or consumers **but**. A prolonged conflict, intensified military activities or more extensive sanctions impacting the **they** region and the resulting economic impact could have a material **materially adversely** effect **affect** on our business, **and operating** results of operations, financial condition, liquidity, growth prospects and business outlook. 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 and operating results as well as those of our customers and suppliers. Natural disasters can impact **us and our operations** customers, as well as **those of our customers and suppliers critical to our operations**. Natural disasters include earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, and other extreme weather conditions that ~~can~~ cause deaths, injuries, and critical health crises, power outages, **property damage** restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures, materials scarcity, price volatility and other ramifications. Climate change is likely to increase **both** the frequency and severity of natural disasters and, consequently, **the** risks to our ~~business and~~ operations **and financial results**. Our digital dental modeling and certain of our customer facing operations are primarily processed in our facilities located in Costa Rica. ~~Our,~~ **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** Our locations in Costa Rica and Mexico as well as others are **susceptible** in earthquake and hurricane zones and may be subject to other natural disasters. Moreover, a significant portion of our research and **their indirect effects** development activities are located in California, which suffers from earthquakes, periodic droughts, heat waves, flooding, power shortages and wildfires. If there is a natural disaster **occurs** in a region where one of these facilities is ~~or those of our~~ **customers or suppliers are** located, our employees could be impacted, ~~our research could be lost, and our ability to create~~

ClinCheck treatment plans, respond to customer inquiries or manufacture and ship our aligners or intraoral scanners could be compromised, **causing** which could result in our customers experiencing significant product and services delays. The effects of climate change on regional and global economies could change the supply, demand or availability of sources of energy or other resources material to our products and operations and affect the availability or cost of natural resources and goods and services on which we and our suppliers rely. **Business and Industry Risks** Demand for our products may not increase or may decrease due to resistance to non-traditional treatment methods, which could have a material impact on our business and operating results. **Our products require our customers to change from traditional treatment methods. For example,** Invisalign treatment ~~represents is~~ a significant change from traditional **orthodontic** metal wires and brackets ~~orthodontic treatment~~, and customers and consumers may not find it cost-effective or preferable ~~to traditional treatment~~. **A** For instance, a number of dental professionals ~~continue to believe the~~ Invisalign treatment is **only** appropriate for ~~only~~ 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 market acceptance of our products depends in part ~~upon~~ on the recommendations of dental professionals, as well as other factors including efficacy, safety, ease of use, reliability, aesthetics, and price compared to competing products and treatment methods. If demand for our products fails to increase, **or decreases, our business,** including due to resistance to nontraditional treatment methods, this could materially affect our ~~business-financial~~ and operating results, **may be harmed**. Our net revenues depend primarily on our Invisalign system and iTero scanners and ~~any decline declines~~ in sales or average selling price of these products may adversely affect net revenues, gross margin and net income. Our net revenues remain largely dependent on sales of our Invisalign system of clear aligners and iTero intraoral scanners. Of the two, we expect **the Invisalign system will continue to account for the majority of our** net revenues ~~from the sale of the Invisalign system, primarily our comprehensive products, will continue to account for the majority of our net revenues~~, making the ~~continued and~~ widespread acceptance of the Invisalign system by orthodontists, GPs and consumers critical to our ~~future success~~. Our iTero business also contributes a material percentage of our overall net revenues. Our CAD / CAM software solutions are important to the continuing evolution of our Align Digital Platform and our business overall. Our operating results could be harmed if: • orthodontists and GPs experience a reduction in consumer demand for orthodontic services; • consumers are unwilling to adopt Invisalign system treatment as rapidly or in the volumes we anticipate and at the prices offered; • orthodontists or GPs choose to continue using wires and brackets or competitive products rather than the Invisalign system or the rates at which they utilize the Invisalign system fail to increase or increase as rapidly as anticipated; • sales of our iTero scanners decline or fail to grow sufficiently or as anticipated; • the growth of CAD / CAM solutions does not produce the results anticipated; or • if the average selling price of our products declines. The average selling prices of our products, particularly ~~our the~~ Invisalign system, are influenced by numerous factors, including the type and timing of products sold (particularly the timing of orders for additional clear aligners for certain Invisalign products) and foreign **currency** exchange rates. In addition, we sell a number of products at different list prices which may differ based on country. Our average selling prices for our Invisalign system and iTero scanners have been impacted in the past and may be adversely affected ~~again~~ in the future if: • we introduce new ~~or~~ **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 ~~any~~ promotions or programs unexpectedly increases ~~or~~, decreases or **drives changes** demand in ~~unexpected and~~ material ways; • our geographic, channel, or product mix shifts to lower priced products or to products **with** that have a higher percentage of deferred revenue; • we decrease 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 pricing regulations such as ~~the~~ volume-based procurement regulations in China; or • estimates used in the calculation of deferred revenue differ from actual average selling prices. **If our 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 gross margins, profitability and** average selling prices ~~decline, our net revenues, gross margin volume growth, and net income may be adversely affected~~. Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that ~~may~~ introduce new technologies or products 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** in a period of immense and rapid digital transformation ~~involving products, technologies, distribution channels and business models~~. While solutions such as our Invisalign system, iTero scanners and CAD / CAM software facilitate this transition, ~~whether our we face competition from companies that also seek to introduce new technologies will achieve market acceptance and products if adopted, whether and when companies that remain dedicated to conventional products. We may be unable to compete with these competitors or they may become render our technology or products obsolete, remains unclear or economically unattractive~~. **Currently, the The number and types of competitors are diverse and growing rapidly. The** Invisalign system competes primarily ~~against with~~ traditional metal wires and brackets and increasingly against clear aligners **which are** manufactured and distributed by new **and existing** market entrants ~~and manufacturers of traditional wires and brackets, including both within and outside the U. S., and from traditional medical device companies, laboratories, startups and, in some cases, doctors and Dental Support Organizations (“DSOs”) themselves. The number and types of competitors are diverse and growing rapidly. They vary by segment, geography, and size, and include new and well-established regional competitors in dental markets, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. Our competitors also include direct-to-consumer (“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 can manufacture custom aligners in their offices using 3D printing technology. Large consumer product companies may also start~~

supplying orthodontic products. **Orthodontists** The manipulation and movement of teeth and bone is a complex and delicate process with potentially painful and debilitating results if improperly performed or monitored. Accordingly, **GPs** we deliver our Invisalign system solutions primarily through trained and skilled doctors. The Invisalign system requires a doctor's prescription and an in-person physical examination of the patient's dentition before beginning treatment; however, with the advent of DTC providers, there has been a shift away from traditional dental practices that may impact our primary selling channels. Doctors and DSOs are sampling **have and may continue to sample competitive and** alternative products and **taking take** advantage of competitive promotions and sale opportunities. In addition, we face competition from companies that introduce new technologies and we may be unable to compete with these competitors or they may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any new technologies, our business could be harmed. Our iTero intraoral scanner **scanners are** can be used to start clear aligner therapy, as well as other dental procedures, including restorative, implant planning and dentures, and also **facing increased competition** functions as a diagnostic tool. The iTero intraoral scanner **scanners competes- compete** with polyvinyl siloxane ("PVS") impressions that doctors use **and numerous new for- or existing** clear aligner therapy or other dental procedures, as well as other intraoral scanners. It **They** also competes- **compete** with traditional bite wing 2D dental x-rays for detecting interproximal caries. If we are unable to compete effectively with **these existing products**, **existing competitors, new market entrants,** or respond effectively to new technologies, our **Systems-business, results of operations** and **Services segment financial condition** could be harmed. To stimulate product and services demand, we have a history of offering volume discounts, price reductions and other promotions to targeted customers and consumers. Whether or not successful, these promotional campaigns have had and may in the future have unexpected and unintended consequences, including reduced gross margins, profitability and average selling prices, net revenues, volume growth, and net income. We cannot assure that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material **materially impacted** effect on our business, results of operations and financial condition. Our success depends on our ability to successfully develop, introduce, achieve market acceptance of, and manage new products and services. Our success depends on our ability to **quickly and** profitably **and quickly** develop, manufacture, market, obtain and maintain regulatory approval or clearance of new products and services along with improvements to existing products and services. **We cannot** There is no assurance --- **assure** we can successfully --- **successful** develop **development**, **sales or** sell and achieve market acceptance of our new or improved products and services. The extent of, and rate at which, new products or services may achieve market acceptance and penetration is a function of many variables, including our ability to: • successfully predict **and,** timely innovate and develop new technologies **and,** applications with the **and products preferred by customers and consumers that have** features and functionality **customers desire or expect to meet the needs of patients**; • successfully, **and in a timely fashion,** obtain regulatory approval or clearance of new and 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 product offerings** from our competitors as well as other products **and services** in our own portfolio and successfully articulate the benefits to our customers; • cost-effectively manage any increased expense of developing, testing, manufacturing and marketing localized versions of our products internationally; • manage the impact of nationalism or initiatives to encourage **encouraging the consumer purchase purchases from** or support of domestic vendors, which can influence customers not to purchase products from, or collaborate to promote interoperability of products with foreign companies; • qualify for third-party reimbursement for procedures involving our products **or services**; • **offer attractive** and **competitive service and subscription plans**; • encourage customers to adopt new technologies and provide the needed technical, sales and marketing support to make new product and services launches successful; **and** • **source and receive quality raw materials or parts from our suppliers**. If we fail to accurately predict **customer-the** needs and preferences **of customers and their patients**, or fail to produce **offer** viable technologies **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 products and product improvements, we may incur substantial costs doing so and our profitability may suffer. **It may be difficult to gain market share and acceptance for new or improved products.** 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. **For instance, it can take up to 24 months or longer to complete treatment using our Invisalign system.** 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 be unsuccessful**, our business, results of operations and financial condition could be materially impacted. We **have in the past and may again in the future** invest in or acquire other businesses, products or, technologies, **or other assets** which may require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations. Periodically, we **have and may in the future** acquire, or make investments in, companies, products or technologies, **or other assets**. Alternatively, we may be unable to find suitable investment or acquisition **opportunities or targets and we may** be unable to complete investments or acquisitions on favorable terms, **if at all**. If we make investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve **our goals or** desired synergies, and 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, 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 **outvoted on** **unable to control or have significant influence over** critical issues that could harm ~~us or~~ the value of our investment. ~~As~~ **Additionally,** 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 which could materially impact our business 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 ~~improprieties, bribery, corruption or other~~ compliance liabilities; • fail to comply with regulations, governmental orders or decrees; • experience IT security and privacy compliance issues; • invest in companies that generate net losses or **are the markets for their products, services or technologies may be slow or fail to develop;** • not realize a positive return on investment or determine that our investments have declined in value, **necessitating we** ~~such that it may be necessary to~~ record impairments such as future impairments of intangible assets and goodwill; • have to pay cash, incur debt or issue equity securities to pay for an acquisition, adversely affecting our liquidity, financial condition or the value 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 ~~would~~ 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 ~~any or all~~ or 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. ~~Moreover, opposition to one or more acquisitions could lead to negative ratings by analysts or investors, give rise to objections by one or more stockholders or result in stockholder activism, any of which could harm our stock price. Business disruptions could seriously harm our financial condition. Our global operations~~ **Operational Risks** have been disrupted in the past and will likely be disrupted and harmed again in the future. The occurrence of any material or prolonged business disruptions, whether internal or at key suppliers, could harm our business and results of operations, result in material losses, seriously harm our revenues, profitability and financial condition, adversely affect our competitive position, increase our costs and expenses, and require substantial expenditures and recovery time in order to fully resume operations. When business disruptions occur, they may, individually or in the aggregate, affect our ability to provide products, services and solutions to our customers, and could cause production delays or limitations, create adverse effects on distributors, disrupt supply chains, result in shipping and distribution disruptions and reduce the availability of or access to one or more facilities. We have policies and procedures which are intended to mitigate the impact of the business disruptions and crises that we believe could be most significant, and we train employees and work with suppliers to prepare for potential disruptions. However, the design or implementation of these policies and practices may fail to adequately address particular disruptions, which could materially and adversely affect our business, ~~financial condition and results of operations.~~ Our operating results have and will continue to fluctuate in the future, which makes predicting the timing and amount of customer demand, our revenues, costs and expenditures difficult. Our quarterly and annual operating results have and will continue to fluctuate for a variety of reasons, ~~including as a result of changing doctor and consumer product demand.~~ In addition to the factors otherwise described herein, some ~~Some~~ of the other ~~the~~ factors that have historically, and could **in the future,** cause our operating results to fluctuate ~~in the future~~ include: • **changes in consumer and doctor demand;** • higher manufacturing, delivery and inventory costs; • the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due; • changes in the timing of revenue recognition and ~~changes in~~ our average selling prices, ~~including as a result of the timing of receipt of product orders and shipments, product and services mix, geographic mix, product and services deferrals, the introduction of new products and software releases, product pricing, bundling and promotions, pricing for fees or expenses, modifications to our terms and conditions such as payment terms, or as a result of new accounting pronouncements or changes to critical accounting estimates including, without limitation, estimates based on matters such as our predicted usage of additional aligners;~~ • seasonal fluctuations; • **improvements**, ~~including those related to patient demographics or changes in~~ or our seasonality as well as **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** ~~availability~~ **available** of doctors to take appointments; • longer customer payment cycles and greater difficulty in accounts receivable collection ~~for our international sales;~~ • costs and expenditures, including **in** connection with the establishment of new treatment planning and fabrication facilities, the hiring and deployment of personnel, ~~and~~ litigation, ~~and;~~ • **the success timing of clear aligner treatment order submission, acceptance, processing and fulfillment, which can cause fluctuations in or our backlog** ~~changes to our marketing programs from quarter to quarter;~~ and • timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows. ~~Failing to accurately predict customer demand may cause us to have inadequate staffing, materials or storage required to manufacture our products to meet demand. If we underestimate~~ **product** demand, it may exceed our manufacturing capacity or that of one or more of our suppliers, we may be understaffed and we may not have sufficient materials ~~needed~~ for production. Specifically, our manufacturing process relies on sophisticated computer software and requires new technicians to undergo a ~~relatively~~ long training process, often 120 days or longer. As a result, if we ~~fail~~ ~~are unable~~ to accurately predict demand, we may have an insufficient number of trained technicians to ~~ensure~~ **timely manufacture and deliver** ~~products are timely manufactured and delivered~~ 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 ~~intraoral iTero scanner~~ **scanners** are generally ~~forecasted 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 lose opportunities to increase revenues and profits, we may have excessive staffing, materials, components and finished products, or capacity. If we hire and train too many technicians in anticipation of demand that does not 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, in order to secure supplies for production of products, we sometimes periodically enter into non-cancelable minimum purchase commitments with vendors, which could impact our ability to adjust our inventory for to reflect declining market demands demand. 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 we may be unable to timely fulfill customer demand. Responding to unanticipated changes in demand the time frames and with the quantities required, any of which may take time to accomplish, lower our gross margin, inhibit sales or harm our reputation. 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 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. 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 and pressure on our internal systems, personnel and suppliers. To In order 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 growing demand for the systems, raw materials, parts and components essential to the product manufacture manufacturing and delivery of our products. We may fail be unable to balance near-term efforts to meet existing demand with future customer demand, including adding personnel, creating scalable, secure and robust systems and operations, and automating processes for long term efficiencies. Production of our Invisalign system clear aligners and iTero intraoral scanners are 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, and limited production yields. Any or all of these problems could result..... needed for long term efficiencies. Any such failure could materially impact our business, 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 facility is temporarily, partially or fully shut down, we may be unable to timely fulfill orders, which may negatively impact our financial results, 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 have previously and could again in the future disrupt our operations and have a material impact on our business, operations and prospects. Additionally, we have established treatment planning and manufacturing facilities closer to our international customers to provide them with better experiences, improve their confidence using our products to treat patients, create efficiencies, and provide redundancy should other facilities be temporarily or our permanently unavailable. Our ability to obtain and maintain regulatory clearance and certifications and equip facilities is subject to significant risk and uncertainty. If a facility is temporarily or permanently, partially or fully shut down, or if demand for our products outpaces our ability to hire qualified personnel and effectively implement systems and infrastructure, we may be unable to fulfill orders timely, or at all, which may negatively impact our financial results, reputation and overall business. Our products and information technology systems are critical to our business. Issues with product development or enhancements, IT system integration, implementation, updates and upgrades have previously and could again in the future disrupt our operations and have a material impact on our business and operating results. We rely on the efficient, uninterrupted and secure operation of our own 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. All software and IT systems are vulnerable to damage, cyber cybersecurity attacks or interruption from a variety of sources. 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, increasingly sophisticated cyber cybersecurity threats, and changing customer preferences. Expanded remote working and increased usage 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 video conferencing applications, 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 entails certain risks, including disruption of our operations, such as our ability to develop and update products that are safe and secure, 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 result in a material materially impact effect on our financial position, results of operations and cash flows. We have a complex, global iTero intraoral scanner installed base of older and newer models. These models are continually updated to add, expand or improve on existing or new features with new hardware improvements, improvements to third-party components, or part to provide repair or replacement parts. 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 not continue to be able unable to

ensure that third party components or any changes to the them foregoing will be compatible with, or will not be incompatible with, or have a negative impact on the functionality of, our iTero intraoral scanners. As a result, there have been and may be widespread failures of our iTero intraoral scanners or we may experience epidemic failures of our iTero intraoral scanner scanners to perform as anticipated. Previously, we have 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 our dependency on third party providers or suppliers. Consequently As a consequence, any remediation has been and may be in the future time- consuming and difficult to achieve, which may materially impact our customers and our business partners, damage our reputation and result in lost business and revenue opportunities, and could be materially costly. Additionally, we continuously upgrade and..... of our customers or our business partners. 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 ours- our or third- party software or other components or systems to interoperate with iTero or third- party scanners, termination of interoperability with third- party 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 for any reason have harmed our operations previously and in the future could materially and adversely affect materially and adversely our ability to accept scans, manufacture clear aligners or restorative procedures or treatments and services or otherwise service our customers. Any of these events which may, amongst other things, harm our sales, damage our reputation, adversely impact our strategic partners or result in litigation. Additionally, we continuously upgrade and issue new releases of our products and customer facing 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 when new versions are 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 intraoral scanners may be exposed to additional vulnerabilities, including increased security risks, errors and malfunctions that may be irreparable or 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 may cause adverse consequences, including: delay or loss of revenues, significant remediation costs, delay in market acceptance, loss of data, disclosure of financial, health or other personal information of our customers or their patients, product recalls, damage to our reputation, loss of market share or increased service costs, any of which could have a material effect on our 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 and operating results could be harmed if supply is restricted or ends, or if the price of raw materials used in our manufacturing process increases. We are highly dependent on our supply chain, particularly manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our intraoral iTero scanners. We maintain single supply relationships for many of these machines and materials. In particular, our CT scanning and stereolithography equipment used in our aligner manufacturing and many of the critical components for the optics of our scanners are provided by single suppliers. We rely on a single third- party manufacturer to supply key sub- assemblies for our iTero Element scanner. We purchase the vast majority of our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, from a single source. By using single suppliers in limited locations for materials and manufacturing in a limited number of locations, we risk are exposed to multiple supply chain vulnerabilities. Because of For example, damage to or our destruction of a facility- dependence on our suppliers, changes in key relationships can materially disrupt our ability to timely deliver key parts, components and materials or products or a supplier could encounter financial, operating or other difficulties, be unable to hire or maintain personnel, fail to timely obtain supplies, fail to maintain manufacturing standards or controls. To the extent any of our suppliers or others' suppliers in our supply chain are dependent on raw materials, components or other parts from Russia or Ukraine, the foregoing risks may be more likely to occur as a result of the military conflict in Ukraine. Any one of these occurrences would adversely impact our supply chain. Because of our dependence on our suppliers, changes in our relationships with any of them can result in disruptions to the supply chain, which can materially impact our business. For instance, we may be unable to quickly establish or qualify replacement suppliers creating production interruptions, delays and inefficiencies. Finding substitute manufacturers may be expensive, time- consuming or impossible and could result in a significant interruption- interruptions in the supply of one or more products, product retesting or additional product registration causing us to lose revenues and suffer damage to our 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 efforts related to our products and services, which exposes us to risks to our sales and, 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. Our distribution agreements with these distributors are generally non- exclusive and terminable by either party with little customary notice. If alternative distributors must 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 in key markets key to our business 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 compliance, safety, data privacy and marketing and sales activities. **The conduct of these distributors also impacts our reputation and our brand. 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 ~~revenues or gross margin~~ **operating and financial results**. We are dependent on commercial freight carriers, primarily UPS, to deliver our products. If the operations of carriers are disrupted **or we fail to mitigate any disruptions**, we may be unable to timely deliver our products to our customers who may choose alternative products, **causing which could cause** our net revenues and gross margin to **decline, possibly** materially decline. For example, after Russia's military attacks in Ukraine in 2022, UPS ceased shipments to Russia and we suspended new product sales there. Moreover, when fuel costs increase, our freight costs generally do so as well. In 2022, due to increased fuel costs, we experienced a material increase in freight costs. In addition, we earn an increasingly larger portion of our total revenues from international sales, which carry higher shipping costs that ~~could~~ 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 ~~in our cost of net revenues~~, our gross margin and financial results could be materially affected. Our success depends largely on the talents and efforts of our personnel. **If** and if we ~~cannot~~ are unable to attract, motivate, train or retain our personnel, it may be more difficult to **achieve** grow effectively and pursue our strategic priorities, ~~and could~~ materially effect **effecting** on our results of operations. We are highly dependent on the talent and ~~effort~~ **efforts** of our personnel, ~~including highly skilled~~. **We strive to retain our** personnel like orthodontists and production technicians in our treatment planning facilities, and employees on our clinical engineering, technology development and sales teams. As a result, 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, ~~there is substantial~~ competition in our industry for highly-skilled personnel **is intense**, in particular **particularly** significantly higher demand for technical and digital talent. Furthermore, ~~and~~ our competitors have and are **likely to continue to recruit our personnel. Our** compensation and benefit arrangements, such as our equity award programs, may not always be successful **successfully** in attracting ~~attract~~ new employees and, retaining ~~retain~~ and ~~or~~ motivating **motivate** existing employees. In addition, other internal and external factors can impact our ability to hire and retain talent, including insufficient advancement or career opportunities and restrictive immigration policies. The loss of any ~~of our~~ key personnel, particularly executive management, ~~key~~ research and development personnel or ~~key~~ sales ~~team~~ personnel, could harm our business and prospects and ~~could~~ impede the achievement of our research and development, operational or strategic objectives. We provide significant training to our personnel and our business will be ~~impacted~~ **harmed** if our training fails to properly prepare ~~them~~ **our personnel** 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 up to twelve months or more to train sales representatives to successfully market and sell our products and for them to establish strong customer relationships.** The loss of the services and knowledge ~~from of~~ our highly-skilled employees may significantly delay or prevent the achievement of our development and business objectives ~~and could harm our business~~. For example, it can take up to twelve months or more to train sales representatives to successfully market and sell our products and for them to establish strong customer relationships. Additionally, ~~facilitating~~ seamless leadership transitions for key positions is a critical **to** factor in sustaining the ~~our~~ culture and **organizational** maintaining the success of our organization. If our succession planning **is** efforts are not effective **ineffective**, it could adversely impact our business. We continue to assess the key personnel that we believe are essential to our long-term success. **Moreover**, as future organizational changes ~~may~~ **could** also cause our employee attrition ~~rate~~ **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, ~~could~~ **may** be harmed. **We** In 2022, we gradually reopened many of our offices that had been substantially closed to employees during the COVID-19 pandemic. Where our offices have reopened, we have adopted a hybrid work schedule **in** that allows many of our **offices, allowing** employees the opportunity to collaborate and connect with others **several** in our offices for some days **each** of the week while ~~having~~ **providing** the option to work remotely other days. This hybrid work approach that we have adopted may materially increase our costs or create ~~unforeseen~~ challenges **with** or complications, including: • difficulties maintaining our corporate culture, **employee satisfaction and** disruption of morale or decreased loyalty; • difficulties with hiring, **promotion**, and retention, particularly if we must compete against other companies that offer generous or broad remote working policies; • negative impacts to collaboration, performance and productivity; • increased stress, fatigue or “burn out” by employees unable to disengage their work life from home life; • increased operational, governance, compliance, and tax risks; • increased attrition or limits to our ability to attract employees who prefer to continue working remotely full time, or in offices or geographies different from where they were hired or are expected to work; • problems managing office space requirements; • concerns regarding favoritism or discrimination; • strains to our business continuity plans and difficulties achieving our strategic objectives; and • increased labor and employment claims and litigation. **We** Also, we believe a key **to** factor in our success has been the culture we have created that emphasizes a shared vision and values focusing on agility, customer success and accountability. We ~~believe this culture fosters an environment of integrity, innovation, creativity, and teamwork~~. We have experienced and may continue to experience in the future, difficulties attracting and retaining employees that meet the qualifications, experience, compliance mindset and values we expect. If we

~~cannot~~ are unable to attract and retain personnel that meet our selection criteria or relax our standards in order to meet the demands of our growth or if our growth is not managed effectively, 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 ~~are~~ **have employees represented by works councils 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 may disrupt our operations and could materially impact our results or operations.** We ~~dependent~~ **depend** on our marketing activities to deepen our market penetration and raise awareness of our ~~brand brands~~ and products, which may ~~not~~ prove ~~successful~~ **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, ~~more recently~~, alliances with professional sports teams, social media influencers and other strategic partners. We ~~attempt to structure our advertising campaigns to increase brand awareness, adoption and goodwill; however, there~~ **There** is no assurance our **advertising** campaigns will achieve the returns on advertising spend desired, increase brand or product awareness sufficiently or generate goodwill and positive reputational goals. Moreover, should any entity or individual endorsing us or our products take actions, make or publish statements in support of, or lend support to events or causes which ~~are~~ **may be** perceived by a portion of society negatively, our sponsorships or support of these entities or individuals may be questioned, ~~boycotts of our products~~ **announced-boycotted**, and our reputation ~~may be~~ **harm**, any of which could ~~have a material~~ **materially** effect on our ~~gross margin~~ **financial results** and business overall. In addition, various countries prohibit certain types of marketing activities. For example, some countries restrict direct to consumer advertising of medical devices. We ~~could run afoul of~~ **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~~. Moreover, competitors do not always follow these restrictions, creating an unfair advantage and making it more difficult and costly ~~for us~~ 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 ~~that~~ we do not control, such as the Android and iOS operating systems, and mobile browsers. ~~Any changes~~ **Changes** in such systems that degrade, ~~reduce~~ or eliminate our ability to target or measure the results of ads or increase costs to target audiences could adversely affect the effectiveness of our campaigns. For example, Apple has released mobile operating **Operating** systems that ~~could also~~ include significant data privacy ~~changes~~ **settings** that may limit our ability to interpret, target and measure ads effectively. We ~~have been incorporating and continue to work to further~~ **incorporate artificial intelligence (“ AI ”) into our products, services and 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 internal operations, which is intended to enhance their operation and effectiveness internally and for our customers, suppliers and consumers. AI innovation presents risks and challenges that could impact our business. Our, or 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. The regulations may impose onerous obligations and may require us to unexpectedly rework or reevaluate improvements to be compliant. Use of AI technologies may expose us to an increased risk of regulatory enforcement and litigation. Moreover, some of the 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 development and deployment practices could subject us to competitive harm, regulatory enforcement, increased cybersecurity risks, reputational harm and legal liability. Legal, Regulatory and Compliance Risks** We are subject to antitrust and competition ~~regulatory regulations~~ activity, litigation and enforcement ~~actions~~ that may result in fines, penalties, restrictions on our business practices, and product or operational changes which could materially impact our business. We ~~currently~~ are and may ~~in the future~~ **in the future** be ~~in the future~~ subject to antitrust, **competition** or **unfair** competition related investigations, enforcement actions ~~or claims~~, and settlements, by governmental agencies, competitors, consumers, customers, and others which, ~~even if unfounded~~, could cause us to incur substantial costs, ~~enter into settlements, consents, be subject to judgments, involve negative publicity, and divert management time and attention, which may materially impact~~ **or our results of operations. Resolving these matters may require us to change our business practices in a manner** ~~materially adverse~~ **ways** to our business. Governments, ~~enforcement authorities and regulators~~ other legislative bodies are actively developing new competition laws and regulations aimed at the technology sector, **AI artificial intelligence** and digital platforms, ~~and~~ coordinating **activities** globally, ~~including and enforcing~~ competition laws and regulations, and this includes scrutiny in potentially large markets such as the EU, U. S., and China. Government regulatory actions and court decisions may result in fines or hinder our ability to provide certain benefits to our consumers, reducing the attractiveness of our products and the revenue ~~derived that comes~~ from them. **These actions and decisions may also hinder our ability to pursue certain mergers, acquisitions, business combinations or Other other companies transactions. We are currently subject to two antitrust actions with jury trials scheduled to begin on May 13, 2024, and government agencies have January 21, 2025. We believe the plaintiffs’ claims are without merit in each of the these past and may actions, but we will likely incur costs in connection with the these future allege trials and with our defense, and there is a risk that we will** our actions violate the antitrust or competition laws or otherwise constitute unfair competition. Such claims and investigations, even if without foundation, may be **subject** very expensive to defend, involve **adverse judgments or** negative publicity and substantial diversion of management time and effort and could result in significant judgments against us or require us to change our business practices, any of which may materially impact our results

of operations. Obtaining approvals and complying with governmental regulations, particularly those related to personal healthcare information, financial information, quality systems, anti-corruption and anti-bribery are expensive and time-consuming. Any failure **Failure** to obtain or maintain approvals or comply with regulations regarding our products or services or **the those** products and services of our suppliers or customers could materially harm our sales, result in substantial penalties and fines 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 of **personal, financial, and** medical information **and as well as** healthcare records; • 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 • the design, manufacture, marketing and advertising of our products. The healthcare and technology markets are also highly regulated and subject to changing political, economic and regulatory influences. Global regulators are expanding and changing the regulations and guidance for products, which can limit the potential benefits of products and **cause result in** protracted review timelines for new **product products** introductions. We are also incorporating artificial intelligence into our software to make it more effective for us, our customers, suppliers and consumers; however, this subjects us to risks of compliance with the expanding and changing regulations regarding the use artificial intelligence. Our critical **third-party** vendors and service providers are similarly subject to various regulations. Our failure or the failure of our suppliers, customers, advertisers 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 **actions alleging allegations of** false or misleading advertising or **other** 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 environmental **and**, health and safety regulations. Additionally, a large portion of our revenues are derived from international sales and we are dependent on our international operations, which exposes us to additional foreign regulations not otherwise described herein, including without limitation, pricing regulations imposed by governments like the volume-based procurement regulations in China. There can be no assurance that 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, **in general** before we can sell a new medical device or market a new use of, or claim for, an existing product, we **frequently** must obtain clearance or approval **to do so** before marketing the product unless an exemption applies. For instance, in the 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 **or and** approvals of products and services from governmental regulators such as the FDA, and there is no guarantee we will successfully or timely **succeed, if at** obtain or maintain approvals in all, **in** or any of the countries in which we do business. In other countries, the requirements, time, effort and expense to obtain and maintain **clearances** similar marketing authorizations may differ materially from those of the FDA. Moreover, these laws may change, resulting in additional time **and**, expense or loss of market access. If approvals **requirements** to market our products or services are delayed, we may be unable to offer them in markets we deem important to our business. 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. **Failure or delays Delays or failures** to obtain or maintain regulatory approvals, **clearances** or to comply with regulatory requirements may materially harm 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 of** regulators and **adhere to applicable** 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 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. 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 **corrupt** payments to foreign officials for the purpose of obtaining or **keeping maintaining** business, securing an advantage and directing business to another. To comply with ABAC laws, regulators require **the maintenance of that we maintain** accurate books and records and a system of internal accounting controls. Under the FCPA, we may be held liable for **any corrupt corruption** actions taken by directors, officers, employees, agents, or other strategic or local partners or representatives. In addition, while we have policies requiring **compliance** our personnel to comply with applicable laws and regulations and we provide significant training to foster compliance, **they our employees, third parties acting on our behalf and customers** may not properly adhere to our policies or applicable laws or regulations, including **such as our policies on** 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, **it could subject us to harm to** our reputation **may be harmed**, **we may** **loss-lose** of customers, **loss or** revenues, or **face** regulatory investigations, actions and fines. Security breaches, data breaches, **cyber cybersecurity** attacks, other cybersecurity incidents or the failure to comply with privacy, security and data protection laws could materially impact our operations, patient care could suffer, we could be liable for damages, and our business, operations and reputation could be harmed. We retain confidential customer personal and financial, patient health information and our own proprietary information and data essential to our business operations. We rely **upon on** the effective **effectiveness** operation of our IT systems, **our policies** and **contracts and policies of our third-party vendors and those** **the IT systems** of our service providers, **vendors**, and other third parties to safeguard the information and data. Additionally, our success **may be dependent depends** on **our** the success of healthcare providers, many of whom are **comprised of** individual or small operations with limited IT experience and inadequate or untested security protocols, **in managing to successfully**

manage data privacy and data security requirements. It is critical that the facilities, infrastructure and IT systems on which we depend ~~to run our business~~ and the products we develop remain secure and be perceived by the marketplace and our customers ~~as to be secure~~. Despite the implementation of security features in our products and security measures in our IT systems, we and our service providers, **third-party** vendors, and other third parties ~~are continue to be~~ targeted by or subject to physical break-ins, computer viruses ~~or and~~ other malicious code, unauthorized or fraudulent access, programming errors or other technical malfunctions, hacking or phishing attacks, malware, ransomware, employee error or malfeasance, ~~cyber-~~**cybersecurity** attacks, and other breaches of IT systems or similar disruptive actions, including by organized groups and nation-state actors. For example, we have experienced, and may again experience in the future, cybersecurity incidents and unauthorized internal employee exfiltration of company information. Further, the frequency **and sophistication** of third-party **cybersecurity** cyber-attacks **is increasing** has increased over the last several years. The military conflict in Ukraine may cause nation-state actors or ~~hackers sympathetic to either side of the conflict to carry out cyber-attacks to achieve their goals, which may include espionage, information gathering operations, monetary gain, ransomware, disruption, and destruction. To respond to potential increases in cyber-attacks, in 2022, we increased efforts to identify and respond to any attacks, including placing our cybersecurity operations team on high alert.~~ Significant service disruptions, breaches in our infrastructure and IT systems or other cybersecurity incidents could expose us to litigation or regulatory investigations, impair our reputation and competitive position, be distracting to ~~our~~ management, and require significant time and resources to address. ~~Affected parties or regulatory agencies could initiate legal~~ **Legal** or regulatory action against us, ~~which~~ could prevent us from resolving the issues quickly or force us to resolve them in unanticipated ways, cause us to incur significant expense and **liability damages**, or result in ~~judicial or governmental~~ orders forcing us to cease operations or modify our business practices in ways that ~~could~~ materially limit or restrict the **capabilities of our** products and services ~~we provide~~. Concerns over our privacy practices could adversely affect others' perception of us and deter customers, ~~and~~ patients and partners from using our products. In addition, patient care could suffer, and we could be liable if our products or IT systems fail to **timely** deliver accurate and complete information **in a timely manner**. We have ~~internal monitoring and detection systems as well as~~ cybersecurity and other forms of insurance coverage related to a **cyber attacks, breach breaches event covering expenses, and other incidents for or security problems notification, credit monitoring, investigation, crisis management, public relations and legal advice. However, damages and claims arising from ~~such specific~~ incidents may not be covered ~~or~~, may exceed the amount of any coverage, and do not cover the time and effort we ~~may~~ incur investigating and responding to any incidents, which may be material. The costs to eliminate, mitigate or recover from security problems and ~~cyber-~~**cybersecurity** attacks and incidents could be material and, depending on the nature and extent of the problem and the networks or products impacted, may result in network or systems interruptions, decreased product sales, or data loss that may have a material impact on our operations, net revenues and operating results. Additionally, our **iTero scanners sold to customers** globally ~~dispersed installed base of iTero intraoral scanners at customer, strategic business partner partners~~ or other locations may be independently or collectively the target of a ~~cybersecurity incident incidents or attack attacks~~ or subject to the intrusion of a ~~virus viruses, bug bugs~~, or other similar negative ~~intruder intruders~~. Due to the large and growing number of these decentralized ~~locations devices~~, we may ~~not be able~~ **unable** to, or not have the capacity, knowledge, or infrastructure ~~to, to~~ respond to or remedy a cybersecurity issue in a timely manner, which may cause loss or damage to us ~~or~~, our customers, or strategic business partners or may cause further malfunctions in, or damage to, our servers, databases, systems or products and services, loss or damage of our data, interruption or temporary cessation of our operations, or an overall negative impact to our business or reputation. We are also subject to federal, state and foreign laws and regulations **respecting**, ~~including regulations affecting~~ the security and privacy of patient healthcare information applicable to healthcare providers and their business associates, such as HIPAA, ~~ones as well as those~~ relating to privacy, data security ~~and protection~~, content regulation, and consumer protection, ~~among others~~. We are subject to various national and regional data localization or data residency laws ~~such as, including U. S. state law, the EU General Data Protection Regulation in the EU and analogous laws in China which generally require that certain types of data collected within a country be stored and processed only within that country or approved countries and, other Other~~ countries are considering enacting similar data localization or data residency laws. 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 to comply with such 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 ~~from one country to another~~. These laws and regulations are constantly evolving and may be **created**, interpreted, applied, ~~created~~ or amended in ~~ways~~ a manner that ~~could~~ adversely affect our business. 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 ~~who may be private individuals~~ or companies, **including** or public entities such as hospitals and clinics, and how we train and support doctors, their staffs and patients who ~~administer or~~ use our products. 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 ~~any our product products~~ we develop or manufacture or services we offer or perform ~~causes~~ **cause** injury or ~~is are~~ otherwise found unhealthy. If our products are safe but they are promoted for use or used in unintended or unexpected ways or for which we have not obtained clearance ~~or approvals~~ ("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 and anticipated environmental, social and governance ("ESG") laws and ~~increased~~ scrutiny of our ESG policies and practices may materially increase our costs, expose us to ~~potential~~ liability, 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 laws and regulations, and we ~~will likely be~~ **and may** be required to comply with new, broader, more complex and more costly ESG laws and regulations ~~that focus on ESG matters~~. Our compliance obligations ~~will likely~~ 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 regulations related to greenhouse gases, **hazardous materials, sustainability and reduction of waste** are expected to have an increasingly larger impact on ~~our us~~ or our suppliers' ~~energy sources~~. Many U. S. and foreign regulators have ~~enacted~~ or are considering enacting new or additional disclosure requirements or limits on the emissions of greenhouse gases, including, ~~but not limited to,~~ carbon dioxide and methane, from power **generated generation units** using fossil fuels. The effects of greenhouse gas emission limits on power generation are subject to significant uncertainties, including the timing of ~~any~~ new requirements, levels of emissions reductions and the scope and types of emissions regulated. ~~These limits may have the effect of~~ **Additionally, laws on sustainability and waste reduction are increasing 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 could which may** result in manufacturing, transportation and supply chain disruptions ~~and delays~~ if clean energy **or sustainable** alternatives are not readily available in adequate amounts when required. Moreover, alternative **clean** energy sources, coupled with reduced investments in traditional energy ~~sources~~ **production** and infrastructure, may ~~not fail to~~ provide the predictable, reliable, and consistent energy that we, our suppliers and other businesses **require need** for operations. Regulations related to **Additionally, the sourcing and availability** of certain metals ~~may have an impact on our business~~. For instance, the sourcing and availability of metals that may be used in the manufacture of, or contained in, our products may be affected by laws and regulations ~~regarding~~ **governing** the use of minerals obtained from certain regions of the world like the Democratic Republic of Congo and adjoining countries. Although we do not believe ~~that we or our suppliers~~ source minerals from this region, **our expanding geographic operations may increase the risk of purchasing "conflict minerals" and our efforts to identify whether any of our products contain minerals impacted by** these laws and regulations may **not be 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 scanners, and the packaging in which they are shipped. These laws are proliferating and new substances subject to restrictions are regularly being added each year. We may be forced 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 ~~for certain metals~~, thereby negatively affecting our ability to manufacture products in sufficient quantities ~~or at~~ competitive prices, leading customers to potentially choose competitive goods and services. Meeting our obligations under existing ESG laws ~~and~~ ~~rules, or regulations is already costly to for~~ us and our suppliers, and we expect ~~those these regulations and~~ costs to increase ~~as new laws are enacted, possibly materially~~. Additionally, we expect regulators to ~~may~~ perform investigations, inspections and periodically audit our compliance with these laws and regulations, and we cannot **be sure** provide assurance that our efforts or operations will 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 ~~to come into compliance~~. ~~Further these laws are subject to unpredictable changes~~. Even if we successfully comply with these laws and regulations, our suppliers may ~~not fail to comply~~. We may also suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are **complaint conflict free**. 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 and results of operations. Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and customers are also increasingly focused on corporate ESG practices. Additionally, public interest and legislative pressure related to ~~public companies' ESG practices continues to grow~~. If our ESG practices fail to meet investor or other industry stakeholders' **frequently** evolving expectations and standards, including environmental stewardship, support for local communities, board of director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be **harmed negatively impacted**, customers and suppliers may be unwilling to do business with us and investors may be unwilling to invest in us. ~~In addition, as we work to align our ESG practices with industry standards, we have expanded and will likely continue to expand our disclosures in these areas. We also expect to incur additional costs and require additional resources to monitor, report, and comply with our various ESG practices~~. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, **comply with or timely** report on our ESG efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our reputation, business, financial performance, growth, and stock price may be adversely impacted. **Intellectual Property Risks** Our success depends in part on our proprietary technology, and if we fail to successfully obtain or enforce our intellectual property ("IP") rights, our competitive position may be harmed. Our success depends in part on our ability to maintain existing IP rights and obtain ~~and,~~ maintain **and enforce** further IP ~~protection~~ **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 U. S. and other countries to protect a large part of our IP and our competitive position; however, these patents may ~~be insufficient to protect our IP rights because our patents may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to~~ prevent third parties from producing

competing products similar in design to our ours products and if they are invalidated, held unenforceable, circumvented, or otherwise limited in scope. Furthermore, our foreign patents- patent protections may be more limited in geographic scope than those provided under U. S. patents- patent and IP laws. Additionally, international IP rights laws are typically less protective than the protections afforded under the laws of the U. S. Additionally, we may fail to timely file a patent application, or any of our patent applications may not result in an issued patent or the scope of the patent ultimately issued may be narrower than we 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 fail to apply for a patent if our personnel fail to disclose or recognize new patentable ideas or innovations. Remote working can decrease the opportunities for our personnel to collaborate, thereby reducing the opportunities for effective 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 could will 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, adversely impact our results of operations and adversely impact our reputation. Extensive litigation over patents and other IP rights is common in medical device, optical scanner, 3D printing and other 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 the those IP rights 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 we 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 types of proceedings can be unpredictable, protracted, time- consuming, expensive and distracting to management and technical personnel. Their outcomes could may adversely affect the validity and scope of our patent or other IP rights, hinder our ability to manufacture and market our products, require us to seek a license licenses for infringing products or technologies or result in the assessment of significant monetary damages. An unfavorable Unfavorable ruling rulings could include monetary damages, an injunction injunctions prohibiting us from selling our products, or an exclusion order orders preventing us from importing our products in one or more countries. Moreover, independent actions by competitors, customers or others have alleged been brought alleging that our efforts to enforce our patent or other IP rights constitute unfair competition or violations of antitrust laws in the U. S. and other jurisdictions 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 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 to earnings. Under U. S. Generally Accepted Accounting Practices ("GAAP"), we review our goodwill at least annually, 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 asset assets group for impairment when events or changes in circumstances indicate the carrying value of the asset (asset group) may not be recoverable. Additionally, goodwill must be tested for impairment at least annually. The qualitative and analysis performed by management to identify indicators of impairment or the quantitative analysis used to test goodwill are dependent upon various determine fair value requires management to exercise significant judgement in determining appropriate assumptions and reflect management's best estimates. Changes in certain assumptions, including revenue growth rates, gross and operating margins, discount rates, earnings multiples and future cash flows may cause a change in circumstances indicating. Management is responsible for continually assessing qualitative factors that could negatively impact the carrying value of goodwill or the asset group may be impaired and assessing these the assumptions and predicting and forecasting future events can be difficult. Goodwill and purchased assets require periodic fair value of goodwill and intangible and long- lived assets and if required, assessments assesses the fair value of each to determine if they have become impaired. Consequently, we may be required to record a material charge to earnings our in the financial statements during the period in which any impairment of goodwill, intangible or long- lived asset 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 GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or in the way these policies are interpreted by us or regulators could ~~have a material~~ **materially** effect on our reported results and may even retroactively affect previously reported 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 ~~effect~~ **affect** our stock price. We are required to furnish in our 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 as to whether ~~it~~ **our internal control over financial reporting** is effective. Our internal controls may become inadequate 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, 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, 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 cause us to lose investor confidence in the accuracy and completeness of our financial reports ~~in the future~~, 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. ~~We are~~ **Align operates globally and is** subject to taxes in the U. S. and foreign countries. Various internal and external factors may affect our future effective tax rate. These factors include changes in the global economic environment, ~~changes in~~ our legal entity structure or activities performed within our entities, ~~changes in~~ our business operations, ~~changes in~~ tax laws, regulations and / or rates, ~~new or~~ **changes** to ~~existing~~ accounting pronouncements, ~~changing~~ interpretations of existing tax laws or regulations, ~~changes in~~ relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, ~~changes in~~ overall levels of pretax earnings, **as well as** the future levels of tax benefits of stock-based compensation, settlement of income tax audits and non-deductible goodwill impairments. ~~Our effective tax rate is also dependent in part on forecasts of full year results which can vary materially.~~ Furthermore, we may continue to experience significant 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** ~~We are subject to tax laws~~ **requires** both within and outside of the U. S. requiring significant judgment **concerning** in determining our worldwide provision for income taxes. Changes in tax laws or changes to how those laws are applied to our business ~~in practice~~, could affect the amount of tax ~~to~~ which we are subject **to** and the manner in which we operate. **Additionally Specifically, in 2016**, the Organization for Economic Cooperation and Development ²⁸ (“OECD”) **established the Inclusive Framework on** Base Erosion and Profit Shifting (“BEPS”) ~~project has resulted in considerable new reporting obligations worldwide as OECD member~~ **to among other things, allocate greater taxing rights to countries where customers are located and establish a global minimum tax rate. After years of evaluating their respective tax laws, many** countries have implemented its enacted changes, or are 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. **If more countries adopt these changes based on the BEPS** guidance. The OECD continues to publish guidance pursuant to the BEPS and other projects which, **our provision for income taxes** if adopted by member countries, may affect our **or operations** tax positions in many ~~may be adversely affected~~ of the countries in which we do business. 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 ~~subject to audits~~ **audited** regarding our tax reporting and remissions by local and national ~~government~~ **governments**, and we may also be subject to audits in ~~U. S. states, local and foreign~~ jurisdictions for which we have not accrued tax liabilities. The positions we take regarding taxes as well as the amounts we collect or remit may be challenged and we may be liable for failing to collect or remit all ~~or any portion of~~ taxes deemed owed or the taxes could exceed our estimates. One or more U. S. states or countries may seek to impose incremental or new sales, use, or other tax collection obligations ~~on us~~ or may determine that such taxes should have but have not been paid by us. If we dispute rulings or positions

taken by tax authorities, we may incur **significant** expenses, and expend significant time and effort to defend our positions ; which may be costly. On August 16 **During the year ended December 31, 2022-2023**, the **Inflation Reduction Act of 2022** **Company received a notice and initial assessment from His Majesty's Revenue and Customs ("IRA-HMRC")** was enacted 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** It contains numerous new U. S. federal tax law provisions, including **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** corporate alternative minimum tax on adjusted financial statement income and an excise tax on corporate stock repurchases, both effective after December 31, 2022. We continue to **unpaid VAT is not probable** evaluate the IRA's impact to our business, which **it is possible that we** may be material **subject to a loss in connection with unpaid VAT**. The application of existing, **and** new, **or future** tax laws, and **the** results of audits ; ~~whether in the U. S. or internationally~~, 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 or changes in our forecasts and guidance; • our ability to regain or sustain our historical growth rates; • changes in recommendations by the investment community or speculation in the press or investment community regarding estimates of our net revenues, operating results or other 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** that may or may not comport with macro, industry or company- specific fundamentals, including ~~without limitation~~, the sentiment of retail investors (**including** 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; • 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, 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; and • general economic market conditions, including rising interest rates, inflationary pressures, recessions, consumer sentiment and demand, global political 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, ~~have often experienced~~ **experience** extreme price and volume fluctuations ~~often~~ unrelated to or disproportionate to corporate operating performance. 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. ~~Historically, securities~~ **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 ~~that~~ 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 ~~Board of Directors'~~ 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** ~~consistent with~~ historical levels or at all, or that our stock repurchase programs will ~~have a beneficial~~ **beneficially** impact on our stock price. Additionally, **the IRA effective January 1, among 2023, other -- the things, Inflation Reduction Act** imposes a 1 % excise tax on **our stock** any domestic corporation that repurchases its stock after December 31, 2022, which will increase our **tax liabilities and the** cost to ~~make repurchases~~ **retire 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 may depress our stock price. **34**