Risk Factors Comparison 2024-02-29 to 2023-03-01 Form: 10-K

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

The following is a summary of the significant risk factors that could materially impact our business, financial condition or future results, including risks related to our businesses, our international operations, our regulatory environments, ownership of our common stock, ~~COVID- 19,~~ and other general risks: • Management **previously** identified material weaknesses in our internal control over financial reporting ~~that~~ **, some of which** resulted in errors in previously issued financial statements. **Although** ~~If we fail to remediate~~ these material weaknesses **have all been remediated as of December 31, 2023, should they recur,** or **if we** ~~experiences~~ **experience** additional material weaknesses in the future, we may be unable to accurately and timely report financial results or comply with the requirements **for** ~~of being a~~ public ~~company~~ **companies** , which could cause the price of our common stock to decline ~~and harm our~~ **or** ~~business~~ **limit our access to the capital markets** . • We ~~restated certain of our previously issued consolidated financial statements, which resulted in unanticipated costs and may affect investor confidence and raise reputational issues. • We~~ may be subject to **additional** litigation and regulatory examinations, investigations, proceedings or court orders as a result of or relating to ~~our~~ **the 2022** internal investigation **which included certain financial reporting matters, which is now complete,** and if any of these items are resolved adversely against us, it could harm our business, financial condition and results of operations. • ~~Our failure to timely file our periodic reports with the SEC limits our access to the public markets to raise debt or equity capital, and restricts our ability to issue equity securities. •~~ Lack of global standardized processes, centralization of transaction management and / or **failures to** ~~execution~~ **execute** could result in control deficiencies and **adversely** impact management' s assertions and financial reporting. • We rely heavily on information and technology to operate both our businesses and our technology dependent product solutions portfolios, and any ~~continued~~ cyber incidents with respect to our ~~supporting~~ information and technology infrastructure, whether by deliberate attacks or unintentional events, could harm our operations **and have a material impact on our business and financial results** . • ~~Privacy concerns and laws, evolving~~ **Evolving** ~~regulation~~ **governmental oversight** of **the use of personal information,** cross- border data transfer restrictions and **the use of AI, as well as** other **technology** regulations **,** may adversely affect our business. • We may be unable to develop innovative products and solutions ~~or~~ **to** stimulate customer demand **. • Damage to our reputation or brand could negatively impact our business, financial condition or results of operations** . • Our ongoing business operations may be disrupted for a significant period of time, resulting in material operating costs and financial losses. • We may be unable to execute key strategic initiatives due to competing priorities and strategies of our distribution partners and other factors, which may result in financial losses and operational inefficiencies. • The success of our business depends in part on achieving our strategic objectives, including through acquisitions, dispositions, and strategic investments and initiatives. • We may fail to realize the expected benefits of our strategic initiatives, including ~~announced~~ **recently executed** or potential future restructuring and **other business** transformation efforts. • We have recognized substantial goodwill and indefinite- lived intangible asset impairment charges ~~, most recently in Q3 and Q4 2022,~~ and may be required to recognize additional goodwill and indefinite-lived intangible asset impairment charges in the future. • Our failure ~~to obtain patents and, consequently,~~ to protect our proprietary technology could have an adverse impact on our competitive position. • Our **financial results may be adversely impacted** ~~profitability could suffer if third parties infringe upon our intellectual property rights or~~ if our products are found to infringe upon the intellectual property rights of others. • Changes in our credit ratings or macroeconomic impacts on credit markets may increase our cost of capital and limit financing options. • A breach of the covenants under our debt instruments outstanding from time to time could result in an event of default under the applicable agreement. • We may not be able to repay our outstanding debt **if** ~~in the event that~~ we do not generate sufficient cash flow to service our debts and cross default provisions may be triggered due to a breach of covenants under our existing indebtedness. • Our foreign currency hedging and cash management transactions may be ineffective or only partially mitigate the impact **of exchange rate fluctuations** , exposing us to unexpected ~~interest rate~~ volatility. • Due to the ~~international~~ **global** nature of our business, including increasing exposure to markets outside of the **United States** ~~U. S.~~ , political or economic changes or other factors could harm our business and financial performance. • ~~Due to our international operations, we are exposed to the risk of changes in foreign exchange rates. •~~ Changes in or interpretations of tax rules, operating structures, transfer pricing regulations, country profitability mix and regulations may adversely affect our effective tax rate. • We may be unable to obtain necessary product approvals and marketing clearances. • **Our doctor- directed, direct to customer clear aligner business could be adversely affected by challenges to our business model or by new state actions restricting our ability to provide our products and services in certain states. •** Inadequate levels of reimbursement from governmental or other third- party ~~payers~~ **payors** for procedures using our products may cause our revenue to decline. • Challenges may be asserted against our products due to real or perceived quality, health or environmental issues. • If we fail to comply with laws and regulations relating to health care fraud, we could suffer penalties or be required to make significant changes to our operations, which could adversely affect our business. • Our business is subject to extensive, complex and changing domestic and foreign laws, rules, regulations, self- regulatory codes, directives, circulars and orders ~~that failure to comply with~~ which, if not complied with, ~~could subject~~ **subjects** us to civil or criminal penalties or other liabilities. • ~~Our~~ **The market price for our common stock may continue to be volatile as a result of a number of factors, including** quarterly operating results ~~and market price for our common stock may continue to be volatile~~ . • Certain provisions in our governing documents, and of Delaware law, may make it more difficult for a third party to acquire us. • Our ~~revenue, results of operations, cash flow, and liquidity may be materially adversely impacted by the ongoing COVID- 19 outbreak. • Our~~ business may be adversely affected by changes in global economic conditions, including inflation, rising interest rates, and

supply chain shortages. • ~~The loss of members of our senior management and the resulting management transition might have an adverse impact on our future operating results. •~~ Talent gaps and failure to manage and retain top talent may impact our ability to **manage our operations, execute strategic initiatives and** grow the business. • We face the inherent risk of **legal actions, including** litigation ~~and~~ **, product liability** claims **, and other regulatory or compliance matters** . • Climate change and related natural disasters could negatively impact our business and financial results. • Expectations relating to environmental, social and governance considerations may expose us to potential liabilities, increased costs, reputational harm, and other adverse effects on our business. Below is a full description of each of such significant risk factors. RISKS RELATED TO OUR ~~RESTATEMENT AND~~ INTERNAL CONTROLS ~~Management identified material weaknesses in internal controls over financial reporting in conjunction with the Audit and Finance Committee' s investigation as described in the Explanatory Note of Amendment No. 1 to the Annual Report on Form 10- K for the fiscal year ended December 31, 2021 (the " 2021 Form 10- K / A "). The~~ description of the material weaknesses that were **remediated during fiscal year** ~~determined to exist as of December 31, 2021~~ **2023** is included under Item 8 of this Form 10- K ~~. Management began implementing the remediation efforts in 2022; however, as of December 31, 2022, the material weaknesses previously identified have not yet been remediated~~ . A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected in a timely basis. ~~While~~ **Although** we **devoted** ~~are devoting~~ substantial resources to the ~~planning and ongoing implementation of~~ remediation efforts to address the identified material weaknesses and prevent additional material weaknesses from occurring, it cannot be assured that the measures we have taken ~~to date, and are continuing to implement,~~ will be sufficient ~~to remediate these material weaknesses or~~ to avoid potential future material weaknesses ~~. We cannot estimate how long the remediation process will take at this time, and may identify deficiencies or other material weaknesses, in addition to the ones already identified, that we may not be able to remediate in a timely manner~~ . Accordingly, there is a reasonable possibility that **a reoccurrence of** the material weaknesses identified **under Item 8 on this Form 10- K** , or other material weaknesses or deficiencies identified in the future, could result in a misstatement of accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis or cause us to fail to meet our obligations under securities laws, stock exchange listing rules, or debt instrument covenants to file periodic financial reports on a timely basis. ~~Further, because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud, even our remediated and effective internal control over financial reporting may not prevent or detect all misstatements and may not provide reasonable assurances with respect to the preparation and presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become either obsolete or inadequate as a result of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.~~ Any ~~of these failures could result in adverse consequences that could materially and adversely affect our business, including an adverse impact on the market price of our common stock, potential action by the SEC, shareholder lawsuits, delisting of our stock, and general damage to our reputation. We have incurred and expect to incur additional costs to rectify the~~ material weaknesses **identified in** ~~or new issues that may emerge, and the existence of these~~ -- **the** ~~issues~~ **future** could adversely affect ~~our reputation or~~ investor **confidence in** ~~perceptions. We maintain director and officer liability insurance, for which we must pay substantial premiums. The additional reporting and other obligations resulting from these material weaknesses, including any litigation or~~ **our** ~~regulatory inquiries that may result therefrom, increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. We restated previously issued consolidated~~ financial statements ~~, which resulted in unanticipated costs and may affect investor confidence and raise reputational issues. As disclosed in Note 1, Significant Accounting Policies and Restatement of the 2021 Form 10- K / A, we restated our consolidated financial statements and related disclosures for the three and nine months ended September 30, 2021 and for the year ended December 31, 2021 following the identification of certain misstatements contained in those financial statements, which resulted in an~~ **and cause** ~~overstatement of Net sales for~~ the **price** ~~fiscal year ended December 31, 2021 by approximately $ 20 million. We determined that it was appropriate to correct the misstatements in our previously issued financial statements by amending and restating the Annual Report on Form 10- K for the fiscal year ended December 31, 2021, originally filed with the SEC on March 1, 2022. The restatement also included corrections for additional identified out-~~ of ~~- period and uncorrected misstatements in the impacted periods. As a result, we incurred unanticipated costs for accounting and legal fees in connection with or~~ **our** ~~related~~ **common stock** to **decline** ~~the restatement, and became subject to a number of additional risks and uncertainties, which may affect investor confidence in the accuracy of our~~ - **or limit** ~~financial disclosures and may raise reputational issues for~~ our ~~business~~ **access to the capital markets** . As previously disclosed **in 2022** , we voluntarily contacted the SEC to advise that the Audit and Finance Committee was conducting an independent investigation regarding certain financial reporting matters, and we are continuing to cooperate with the SEC. The SEC ~~'~~ **'** s investigation is ongoing ~~and was not resolved when the Audit and Finance Committee completed the internal investigation or when the 2021 Form 10- K / A was filed. We intend to fully cooperate with the SEC regarding this matter~~ . Additionally, several securities class action lawsuits were filed against us following our announcement on May 10, 2022 of the Audit and Finance Committee ~~'~~ **'** s internal investigation. ~~Our~~ **As a result of the previously** reported material weaknesses in internal control over financial reporting ~~subjects us to~~ **which have been remediated as of December 31, 2023, we may face** additional litigation and regulatory examinations, investigations, proceedings or court orders, including additional cease and desist orders, the suspension of trading of our securities, delisting of our securities, the assessment of civil monetary penalties and other equitable remedies. Our management has devoted and may be required to **further** devote significant time and attention to these matters. If any of these matters are resolved adversely against us, it could harm our reputation, business, financial condition and results of operations. Additionally, while we cannot estimate our potential exposure to these matters at this time, we have already expended a significant amount of time and resources investigating the claims underlying and defending these matters and expect

to continue to ~~need to~~ expend our resources to conclude these matters. Accordingly, the ongoing SEC investigation and any ~~potential~~ related litigation could result in distraction to management and entail risks and uncertainties, the outcome of which could adversely affect our results of operations and our reputation. For further information, see Note ~~22~~ **21** , Commitments and Contingencies, discussing the securities class action lawsuits, in the Notes to Consolidated Financial Statements in Item 8 of this Form 10- K. We ~~did not timely file our Quarterly Reports on Form 10- Q for the fiscal quarters ended March 31, 2022 and June 30, 2022 within each respective timeframe required by the SEC. This limits our ability to access the public markets to raise debt or equity capital, which could prevent us from pursuing transactions or implementing business strategies that we might otherwise believe are beneficial to our business. We are not currently eligible to use a registration statement on Form S- 3 that allows us to continuously incorporate by reference our SEC reports into the registration statement, or to use " shelf " registration statements to conduct offerings, until approximately one year from the date we regained status as a current filer. If we wish to pursue a public offering now, we would be required to file a registration statement on Form S- 1 and have it reviewed and declared effective by the SEC. Doing so would take significantly longer than using a registration statement on Form S- 3 and would increase our transaction costs, and the necessity of using a Form S- 1 for a public offering of registered securities could, to the extent we are not able to conduct offerings using alternative methods, adversely impact our ability to raise capital or complete acquisitions of other companies in a timely manner. Our implementation of our business plans, restructuring plans and compliance with regulations requires that we effectively manage our financial infrastructure, including standardizing processes, maintaining proper financial reporting and internal controls. We continue to focus on standardizing our processes, improving our financial systems, maintaining effective internal controls and centralizing transaction management and / or execution so as to provide continued assurance with respect to our financial reports, support the continued growth of the business, and prevent financial misstatement or fraud. Non- standardized processes and ineffective controls could result in an inability to aggregate and analyze data in a timely and accurate manner and may lead to inaccurate or incomplete financial and management reporting and delays in financial reporting to management, regulators and / or shareholders. Inaccurate or incomplete financial reporting and disclosures could also result in noncompliance with applicable business and regulatory requirements and the incurring of related penalties. For further information in connection with the risks of inaccurate or incomplete financial reporting and disclosures, see Item 1A. Risk Factors — Risks Related to Our Restatement and Internal Controls — " Management identified material weaknesses in our internal control over financial reporting that resulted in errors in financial statements. If we fail to remediate these material weaknesses or experiences additional material weaknesses in the future, we may be unable to accurately and timely report financial results or comply with the requirements of being a public company, which could cause the price of our common stock to decline and harm our business. " Further, we~~ currently have disparate systems, including ~~enterprise~~ **Enterprise** ~~resource~~ **Resource** ~~planning~~ **Planning (" ERP ")** systems, across the organization which may result in the potential inability to obtain and analyze business data and increases in budgets due to higher costs stemming from system upgrades, and may pose business partner connection challenges. **Non- standardized processes and ineffective controls could result in an inability to aggregate and analyze data in a timely and accurate manner and may lead to inaccurate or incomplete financial and management reporting and delays in financial reporting to management, regulators and / or shareholders. Inaccurate or incomplete financial reporting and disclosures could also result in noncompliance with applicable business and regulatory requirements and the incurring of related penalties or fines.** As a result, the data required to manage the business may not be complete, accurate or consistent, resulting in the potential for misleading or inaccurate reporting for key business decisions. **We continue to focus on standardizing our processes, improving our financial systems, maintaining effective internal controls and centralizing transaction** ~~Management~~ **management and execution so as to provide continued assurance with respect to our financial reports, support the continued growth of the business, and prevent financial misstatement or fraud. In 2023, we began a process of implementing a new global ERP system, which will upgrade and standardize our existing information systems. However, this new ERP system will take several years to implement, will require significant resources to integrate with the Company** ' s ~~planned efforts to implement a more centralized enterprise resource planning system across the~~ **other** ~~organization~~ **business processes, and even at its completion may not be fully successful** in ~~part~~ **providing standardization sufficient** to ~~alleviate~~ **address** these risks ~~will result in additional costs in~~ **once completed. For further information, refer to the risk factor titled " We may fail to realize the expected benefits of our strategic initiatives, including recently executed or potential** future **restructuring** ~~periods,~~ and ~~any cost overrun or any disruptions, delays or complications in the~~ **other** ~~course of making this transition could compound those costs, distract from operation of our core~~ business ~~, or result in failures to produce financial information~~ **transformation efforts** ~~accurately and timely~~ . **"** RISKS RELATED TO OUR BUSINESSES We are exposed to the risk of cyber incidents, which can result from deliberate attacks or unintentional events, in the normal course of business. We use web- enabled and other integrated information and technology systems ~~in~~ **to manage our business, and** ~~delivering~~ --- **deliver** ~~our~~ products and services ~~and~~ **to customers. In particular, the 2022 launch of our cloud solution DS Core, a platform that integrates digital dentistry workflows across devices, has introduced new potential vulnerabilities to cyber attacks within our service delivery model. We** expect that the breadth and complexity of our information and technology systems will increase as we expand **the services enabled by the DS Core platform and further develop** our **ERP systems and** product offerings to utilize artificial intelligence **(" AI ")** and analytics. As a result, we will increasingly be exposed to risks inherent in the development, integration and operation of ~~our~~ **the** evolving information and technology supporting our product platforms, as well as our own internal infrastructure, including: • security breaches, viruses, cyberattacks, ransomware or other malware or other failures or malfunctions; • disruption, impairment or failure of data centers or hardware, telecommunications facilities or other infrastructure platforms; • failures during the process of upgrading or replacing software, databases or components contained in the information and technology infrastructure; • the compromise or unauthorized disclosure of sensitive or proprietary information related to our business and customers; • excessive costs, excessive delays or other deficiencies in systems

development and deployment; and • an unintentional event that involves a third- party gaining unauthorized access to our systems or proprietary information. **We also utilize systems, applications and data storage provided and maintained by third parties, including those delivered through cloud- based solutions.** Any disruptions to or deterioration of our **distribution partners' or** service providers' information and technology infrastructures could pose a threat to our operations and harm our business. We continue to ~~observe~~ **experience** an increase in ~~levels of~~ cyber threats focused on gaining unauthorized access to our information and technology infrastructure for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Although we take measures designed to protect such information from unauthorized access, use or disclosure, our and our service providers' infrastructures and storage applications may be impaired due to unauthorized access by hackers, ransomware, phishing attacks, human error, malfeasance, natural disasters, telecommunications and electrical failures and other disruptions. Cyber threats are rapidly evolving and are becoming increasingly sophisticated, with an increase in **the frequency of** cyber incidents ~~that appear to be associated with the Ukraine- Russia military conflict~~ . Like other large, global companies, during the normal course of business, we have experienced and expect to continue to experience cyber threats, attacks and other attempts to compromise our information system, although none, to our knowledge, has had a material adverse effect on our business, financial condition or results of operations to date. Anyone who circumvents our security measures could misappropriate proprietary information, including information regarding us, our employees, our service providers and / or our ~~clients~~ **customers** , or cause interruptions in our operations. We cannot provide assurances that, although past cybersecurity incidents have not had a material effect on our business or operations to date and despite our efforts to ensure the integrity of our systems and the measures that we or our service providers take to anticipate, detect, avoid or mitigate such threats, a future **cyberattack** ~~cyber- attack~~ would not result in material harm to us or our business and results of operations. For example, certain techniques used to obtain unauthorized access, introduce malicious software, disable or degrade service, or sabotage systems may be designed to remain dormant until a triggering event **occurs** and we may be unable to anticipate these techniques or implement adequate preventive measures since techniques change frequently or are not recognized until launched, and because **cyberattacks** ~~cyber attacks~~ can originate from a wide variety of sources. These data breaches and any unauthorized access or disclosure of our information could compromise intellectual property and expose sensitive business information. Our policies, employee training (including phishing prevention training), procedures and technical safeguards may be insufficient to prevent or detect improper access to confidential, proprietary or sensitive data, including personal data. **Cyberattacks** ~~Cyber attacks~~ could also cause us to incur significant ~~remediation~~ costs **to recover from breaches** , disrupt key business operations and divert attention of management and key information technology resources. We also face the ongoing challenge of managing access controls to our information and technology infrastructure. We have experienced various types of cyber incidents in the past and as the result of such incidents, we have implemented new controls, governance, technical protections and other procedures. If we do not successfully manage these access controls, it could expose us to risk of security breaches or disruptions. Any such security breaches or disruptions could compromise the security or integrity of our networks or result in the loss, misappropriation, and / or unauthorized access, use, modification or disclosure of, or the prevention of access to, sensitive data or confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information). If our information systems are breached again, sensitive and proprietary data is compromised, surreptitiously modified, rendered inaccessible for any period of time or made public, or if we fail to make adequate or timely disclosures to affected individuals, appropriate state and federal regulatory authorities or law enforcement agencies, it could result in significant fines, penalties, court orders, sanctions and proceedings or actions against us by governmental or other regulatory authorities, customers or third parties. We may incur substantial costs and suffer other negative consequences such as liability, reputational harm and significant remediation costs and experience material harm to our business and financial results if we experience cyber incidents in the future. **AI- based platforms and tools are increasingly being used in the consumer health industries, and our use of this technology, as well as its use by our business partners with access to our confidential information, including trade secrets, may continue to increase and could lead to the unintentional release of such information, which could negatively impact us, including our ability to realize the benefits of our intellectual property. Additionally, the advancement of AI and large language models has given rise to additional vulnerabilities and potential entry points for cyber threats. With generative AI tools, threat actors may have additional tools to automate breaches or persistent attacks, evade detection, or generate sophisticated phishing emails. Our use of AI and the use of AI by our business partners may lead to novel and urgent cybersecurity risks, which could have a material adverse effect on our operations and reputation as well as the operations of any of our business partners.** The materialization of any of these risks may impede the utilization of **the** Company **' s** product offerings, the processing of data and the day- to- day management of our business and could result in the corruption, loss or unauthorized disclosure of proprietary, confidential or other data. Disaster recovery plans, where in place, might not adequately protect us in the event of a system failure. Further, we currently do not have excess or standby computer processing or network capacity everywhere in the world to avoid disruption in the receipt, processing and delivery of data in the event of a system failure. Despite any precautions we take, damage from fire, floods, hurricanes, power loss, telecommunications failures, computer viruses, break- ins, human error ~~and~~ **or** similar events at our various computer facilities could result in interruptions in the flow of data to our servers **, although we have not yet experienced such an interruption** . Additionally, we seek to maintain insurance coverage for risks associated with cybersecurity, but such insurance has become increasingly difficult to secure and, in some cases, policies may not provide adequate coverage for possible losses. Further, as cybersecurity risks evolve, such insurance may not be available to us on commercially reasonable terms or at all. Uninsured losses or operational losses that result from large deductible payments under commercial insurance coverage might have an adverse impact on our business operations and our financial position or results of operations. ~~The legislative and regulatory framework~~ **Any of the foregoing incidents could also subject us to liability, expose us to significant expense,** ~~for~~ **or** ~~privacy~~ **cause significant harm to our reputation** and **result in lost revenue. While we**

have invested and continue to invest in information technology risk management and disaster recovery plans, these measures cannot fully insulate us from cyber incidents, technology disruptions or data ~~protection issues worldwide continues to evolve~~ **loss and the resulting adverse effect on our operations and financial results** . We collect personally identifiable information (~~"~~ **“** PII ~~"~~ **”**) and other data as part of our business processes and activities. This data is subject to a variety of U. S. and foreign laws and regulations, including oversight by various regulatory or other governmental bodies. Many foreign countries and governmental bodies have laws and regulations concerning the collection and use of PII and other data obtained from their residents or by businesses operating within their jurisdictions. The EU General Data Protection Regulation (~~"~~ **“** GDPR ~~"~~ **”**), for example, imposes stringent data protection requirements and provides significant penalties for noncompliance. Any inability, or perceived inability, to adequately address privacy and data protection concerns, even if unfounded, or comply with applicable laws, regulations, policies, industry standards, contractual obligations, or other legal obligations (including at newly acquired companies) could result in additional cost and liability to us or our ~~officials~~ **officers** , damage our reputation, inhibit sales, and otherwise adversely affect our business. ~~Any of the foregoing incidents could also subject us to liability, expose us to significant expense, or cause significant harm to our reputation, all of which could result in lost revenue. While we have invested and continue to invest in information technology risk management and disaster recovery --~~ **Moreover** ~~plans , these measures cannot fully insulate us from cyber incidents, technology disruptions or data loss and the resulting adverse effect on our operations and financial results. Global~~ **global** regulation related to the provision of services on the Internet is increasing, as federal, state and foreign governments continue to adopt new laws and regulations addressing data privacy and the collection, processing, storage and use of personal information. Such laws and regulations are subject to new and differing interpretations and may be inconsistent among jurisdictions. These and other requirements could reduce demand for our **products or** services or restrict our ability to store and process data or, in some cases, impact our ability to offer future digital dentistry **products and** services in certain locations or our ability to deploy our solutions globally. The costs of compliance with and other burdens imposed by these types of laws, regulations and standards may limit the use and adoption of our **products or** services, reduce overall demand for our **products or** services, lead to significant fines, penalties or liabilities for noncompliance, any of which could harm our business. The importance of privacy laws, rules and regulations specifically for the healthcare and **medical device** ~~med- tech~~ industry is constantly growing, as personal data has become an integral part of doing business in our sector, and the legal standards are evolving and becoming more complex worldwide. For instance, the GDPR, applicable as of 2018 and still one of the strictest and most comprehensive privacy laws in the world, is being continuously enforced, and ~~increasingly heavy~~ fines are now **increasingly** being levied on businesses. Fines for noncompliance with the GDPR can amount to up to € 20 million or 4 % of the total worldwide annual ~~turnover~~ **sales** from the preceding financial year (whichever is higher) and may be imposed in conjunction with the exercise of the authority ~~'~~ **’** s investigatory and corrective powers. The GDPR ~~'~~ **’** s extraterritorial scope makes it applicable to our U. S. **-** based legal entities whenever our business activities, systems and products process the personal data of EU residents. Additionally, privacy laws, rules and regulations are also rapidly developing in other regions, including China, Brazil ~~,~~ **and** South Korea, and is expanding through the **United States** ~~U. S.~~ , state by state (e. g., California, Virginia, Colorado, Connecticut, and Utah), in parallel with federal privacy laws protecting sensitive health information. These varying laws, rules, regulations and industry standards impact our businesses to the extent we rely on the use of personal data and create significant compliance challenges while maintaining our global reach. In addition, certain privacy and data protection laws may apply to us indirectly through our customers, manufacturers, suppliers or other third- party partners. For example, non- compliance with applicable laws or regulations **by** a third- party partner that is processing personal data on our behalf may be deemed non- compliance by us or a failure by us to conduct proper due diligence on the third party. **In** ~~We also could be subject to additional --~~ **addition,** ~~expenses and liabilities in~~ the **legal** ~~event of an~~ **and** ~~information security incident,~~ **regulatory landscape surrounding AI technologies is rapidly evolving and uncertain** including ~~a~~ **in the areas of intellectual property,** cybersecurity ~~breach , or the failure of an and information technology system owned~~ **privacy and data protection.** ~~or~~ **For** ~~operated~~ **example, there is uncertainty around the validity and enforceability of intellectual property rights related to the use, development, and deployment of AI** by us **and by** ~~or~~ **our business partners. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant operational costs and may limit the ability of the Company and our business partners to develop, deploy or use AI technologies. Failure to appropriately respond to this evolving landscape may result in legal liability, regulatory action, or brand and reputational harm. New and more stringent multinational, national and state technology legislation and regulations may be adopted in 2024 and beyond. We cannot predict all the jurisdictions in which new legislation, regulation or enforcement might arise, the scope of such legislation, regulation and enforcement, or the potential impact to our business and operations of any such changes. Failure to comply with U. S. and international technology laws and regulations could result in government enforcement actions (which could include substantial civil and / or criminal penalties and injunctive relief), private litigation and / or adverse publicity and could have** a **material adverse impact on** ~~third party with which we partner or~~ **our** ~~its vendor~~ **business, financial condition or results of operations** . The worldwide markets for dental and ~~medical~~ **continence care** products ~~is~~ **are** highly competitive and ~~is driven by~~ **are subject to** rapid and significant technological **disruption through new product introductions,** ~~change~~ **changes** ~~, change~~ in consumer preferences, **and** ~~new intellectual property associated with that technological change,~~ evolving industry standards ~~,~~ and **best practices** ~~new product introductions. Additionally, some markets for products are also subject to significant negative price pressures~~ . Our patent portfolio continues to change with patents expiring through the normal course of their life. There can be no assurance that our products will not lose their competitive advantage or become noncompetitive or obsolete as a result of such factors, or that we will be able to generate any economic return on our investment in product development. If product demand decreases, or if our newly introduced products are not accepted by our customers, our revenue and profit could be negatively impacted. Important factors that could cause demand for our products to decrease include changes in: • business conditions,

including downturns in the dental industry, regional economies, and the overall economy; • the level of customers' inventories; • competitive and pricing pressures, including actions taken by competitors; and • customer product needs and customer / patient lifecycle. If we fail to ~~further~~ **innovate existing technologies or** develop ~~our innovation efforts~~ **new technologies through** ~~or~~ **our research and development process consistent with changing** ~~if our R & D does not effectively respond to changes in~~ consumer preferences or ~~market~~ **to differentiate our products relative to our** competition ~~leading to~~ **, our** technology or ~~product~~ **products** ~~obsolescence, we~~ may **become obsolete and cause us to** lose market share and revenue. ~~Additionally, if our products or technologies lose their competitive advantage or become noncompetitive or obsolete, our business could be negatively affected.~~ We have identified **the development of** new **technologies and** products as an important part of our growth ~~opportunities~~ **strategy** . There is no assurance that entirely new technology or approaches to dental treatment or competitors' new products will not be introduced that could render our products obsolete **, and there is no assurance that capital allocated to R & D will yield expected benefits** . Additionally, the rapid pace of technological advancements may accelerate **amortization** ~~the need to amortize or impair investments in our software technology~~ faster than we anticipated **or impair investments in our software technology** , which could negatively impact our results **. We seek to maintain our reputation for delivering innovative and effective solutions to advance patient care and deliver better, safer, and faster dentistry and continence care under a strong portfolio of world- class brands. Successful promotion of our brand depends on multiple factors, including our marketing efforts and our ability to deliver a superior customer experience, develop innovative products, and successfully differentiate our offerings from those of our competitors. Additionally, the strength of our brand relies on continued effective use of our distribution network and customer service platforms. The promotion of our brand requires us to make substantial expenditures, including recent investments in enhancing customer experience, and we anticipate the need for such expenditures to continue. Our brand promotion activities may not be successful in maintaining our current level of revenue or yielding increased revenue. If we do not successfully position our brand and reputation as an industry leader, our business and operating results may be adversely affected. Additionally, our brand depends on our reputation for offering high- quality solutions meeting the highest of safety standards. To safeguard that reputation, we have adopted rigorous quality assurance and quality control procedures which are designed to ensure the safety of our products, including incremental investments in improved quality control during the course of 2023. A serious breach of our quality assurance or quality control procedures, deterioration of our quality image, impairment of our customer or consumer relationships or failure to adequately protect the relevance of our brands may lead to litigation, customers purchasing from our competitors, or consumers purchasing other brands or private label items not manufactured by us, any of which could have a material negative impact on our business, financial condition or results of operations** . We operate in more than 150 countries and our and our suppliers' manufacturing facilities are located in multiple locations around the world. Potential events such as extreme weather, natural disasters, **regional epidemics or global pandemics,** worker strikes and social and political actions, such as trade wars, **regional wars or conflicts** or other events beyond our control, could impact our ongoing business operations, including potential critical third- party vendor disruptions or failure to adhere to contractual obligations affecting our supply chain and manufacturing needs or the loss of critical information technology and telecommunications systems. Although we maintain multiple manufacturing facilities, a large number of the products manufactured by us are manufactured in facilities that are the sole source of such products. As there are a limited number of alternative suppliers for these products, any disruption at a particular Company manufacturing facility could lead to delays, increased expenses, and may damage our business and results of operations. If our incident response, disaster recovery and business continuity plans do not resolve these issues in an effective and timely manner, such events could result in an interruption in our operations and could cause material negative impacts to our product availability and sales, the efficiency of our operations and our financial results. Additionally, a significant portion of our injectable anesthetic products, orthodontic products, certain dental cutting instruments, catheters, nickel titanium products and certain other products and raw materials are purchased from a limited number of suppliers and in certain cases single source suppliers pursuant to agreements that are subject to periodic renewal, some of which may also compete with us. As there are a limited number of suppliers for these products, there can be no assurance that we will be able to obtain an adequate supply of these products and raw materials in the future. Any delays in delivery of or shortages in these products could interrupt and delay manufacturing of our products and result in the cancellation of orders for these products. In addition, these suppliers could discontinue the manufacture or supply of these products to us at any time or supply products to competitors. We may not be able to identify and integrate alternative sources of supply in a timely fashion or at all. Any transition to alternate suppliers may result in delays in shipment and increased expenses and may limit our ability to deliver products to customers. We continue to generate a substantial portion of our revenue through a limited number of distributors that provide important sales, distribution and service support to the end- user customers. Together, our two largest distributors, Patterson and Henry Schein, accounted for approximately ~~17~~ **21** % of our annual revenue for the year ended December 31, ~~2022~~ **2023** , and it is anticipated that they will continue to be the largest distribution contributors to our revenue through ~~2023~~ **2024** . We may be unable to execute our key strategic activities and investments due to **operation disruptions impacting our distributors or** the competing priorities of our distribution partners which may introduce **additional** competing private label, generic, or low- cost products that compete with our products at lower price points ~~, particularly in the Technologies & Equipment segment products that are sold and serviced through distributor channels~~ . If these competing products capture significant market share or result in a decrease in market prices overall, this could have a negative impact on our results of operations and financial condition. Additionally, some parts of the dental market continue to be impacted by price competition that is driven in part by the consolidation of dental practices, **the growing significance of DSOs,** innovation and product advancements, and the price sensitivity of end- user customers. There can be no assurance that our distribution partners will purchase any specified minimum quantity of products from us or that they will continue to purchase any products at all. If Patterson or Henry Schein ceases to purchase a significant volume of products from us, or if changes in

our promotional strategies and investments result in changes in our distributor relationships ~~or short- term uneven growth~~ , it could have a material adverse effect on our results of operations and financial condition. We rely in part on our ~~dealer~~ **distributor** and customer relationships and predictions of ~~dealer~~ **distributor** and customer inventory levels in projecting future demand levels and financial results. These inventory levels may fluctuate, and may differ from our predictions, resulting in our projections of future results being different than expected. These changes may be influenced by changing relationships with **distributors** ~~the dealers~~ and customers, economic conditions and customer preference for particular products. There can be no assurance that ~~dealers~~ **distributors** and customers will maintain levels of inventory in accordance with our predictions or past history, or that the timing of customers' inventory build- up or liquidation will be in accordance with our ~~predictions~~ **expectations** or ~~past history~~ **historical experience** . Additionally, we periodically upgrade or replace our various software systems, including our customer relationship management systems. If we encounter unforeseen problems with new systems or in migrating away from our existing applications and systems, our operations and our ability to manage our business could be negatively impacted. **Any disruptions to our distributors' operations or systems may result in delays in orders and shipments, and prevent our products from being timely delivered to the market.** We utilize and intend to continue utilizing acquisitions and dispositions of assets and businesses, and strategic investments as part of our strategy. We may not achieve expected returns and benefits in connection with this strategy as a result of various factors, including integration and collaboration challenges, such as personnel and technology. In addition, we may not achieve the full revenue growth expectations and cost synergies anticipated to result from related integration activities. ~~Further, acquisitions~~ **Acquisitions** , dispositions and strategic investments may distract our management' s time and attention and disrupt our ongoing business operations or relationships with customers, employees, suppliers or other parties. We continue to evaluate the potential disposition of assets and businesses that may no longer help us achieve our strategic objectives, and to view acquisitions as a key part of our growth strategy. After reaching an agreement with a seller for the acquisition or buyer for the disposition of assets or a business, the transaction may remain subject to necessary regulatory and governmental approvals on acceptable terms as well as the satisfaction of pre- closing conditions, which may prevent us from completing the transaction in a timely manner, or at all. ~~From a workforce perspective, risks associated with acquisitions and dispositions include, among others, delays in anticipated workforce reductions, additional unexpected costs, changes in restructuring plans that increase or decrease the number of employees affected, negative impacts on our relationship with labor unions, adverse effects on employee morale, and the failure to meet operational targets due to the loss of employees, any of which may impair our ability to achieve anticipated cost reductions or may otherwise harm our business, and could have a material adverse effect on our competitive position, results of operations, cash flows or financial condition.~~ When we decide to sell assets or a business, we may encounter difficulty in finding buyers or executing alternative exit strategies on acceptable terms in a timely manner, which could delay the accomplishment of our strategic objectives. Alternatively, we may dispose of a business at a ~~price~~ **valuation** or on terms that are less **favorable** than we had anticipated, or with the exclusion of select assets. Dispositions may also involve continued ~~financial~~ involvement in a divested business, such as through continuing equity ownership, transition service agreements, guarantees, indemnities or other current or contingent financial obligations. Under these arrangements, **the** performance ~~by~~ **of** the acquired or divested business, or other conditions outside our control, could affect our future financial results. Additionally, if we make acquisitions, ~~it~~ **they** may incur debt, assume contingent liabilities and / or additional risks, or create additional expenses, any of which might adversely affect our financial results. Any financing that we might need for acquisitions may only be available on terms that restrict our business or that impose additional costs that reduce our operating results. In order to operate more efficiently and control costs, **during the course of 2023,** we ~~recently announced our plans to make~~ **made** organizational restructuring changes in order to simplify structure, enhance profitability, improve operational performance and drive growth. These plans ~~include~~ **included** implementation of a new operating model with five global business units designed to drive enterprise integration and align the product portfolio with our growth strategy, commencement of our central functions and infrastructure optimization to support efficiency of the overall organization, ~~creation of a Senior Vice President of Quality and Regulatory role, designed to elevate the quality and regulatory affairs function within the management team, simplification of the management structure to bring the Company in- line with the industry best practices,~~ and other initiatives aimed at delivering cost savings to fund critical investments in 2023 and to position the Company for sustainable future growth. The failure to ~~efficiently~~ execute such initiatives as part of our business strategy could minimize the expected benefits to the organization resulting in potential **adverse** impacts to ongoing operations and cost overruns. **As part of these initiatives, we are in the process of implementing a new global ERP system, which will upgrade and standardize our existing information systems. In 2023, we started to make capital investments in this system which has resulted in significant costs and uses of cash, and which will continue to result in additional costs and uses of cash in future periods. Implementation is expected to take several years to complete. Cost overruns or any disruptions, delays or complications in the course of making this transition could lead to higher than anticipated capital investments and related costs, distract from the operation of our core business, or result in failures to produce financial information accurately and timely. Additionally, any delay or other failure to achieve our implementation goals may adversely impact our financial results. The failure to either deliver the application on time or anticipate the necessary readiness and training needs could lead to business disruption and loss of business. Failure or abandonment of any part of the ERP system could result in a write- off of part or all of the costs that have been capitalized on the project.** Additionally, our ability to achieve the benefits from ~~these~~ **any of our strategic** initiatives within the expected time frame is subject to many estimates ~~and~~ **,** assumptions and other factors that we may not be able to control. We may also incur ~~significant~~ charges related to restructuring plans **that are higher than anticipated** , which would reduce our profitability in the periods such charges are incurred. Due to the complexities inherent in implementing these types of cost reduction and restructuring activities, and the **timing** ~~quarterly phasing~~ of ~~related~~ **strategic** investments, we may fail to realize expected efficiencies and benefits, such as the goals for net sales

growth **or operating margins** , or may experience a delay in realizing such efficiencies and benefits, and our operations and business could be disrupted. Company management may be required to divert their focus to managing these disruptions, and implementation may require the agreement of third parties, such as labor unions or works councils. Risks associated with these actions and other workforce management issues include delays in implementation of anticipated workforce reductions, additional unexpected costs, changes in restructuring plans that increase or decrease the number of employees affected, negative impact on our relationship with labor unions or works councils, adverse effects on employee morale, and the failure to meet operational targets due to the loss of employees, any of which may impair our ability to achieve anticipated cost reductions or may otherwise harm our business, and could have a material adverse effect on our sales growth and other results of operations, cash flows or financial condition, or competitive position ~~. We review amortizable intangible assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable~~ . We test goodwill and indefinite- lived intangibles for impairment at least annually. The valuation models used to determine the fair value of goodwill or indefinite- lived intangible assets are dependent upon various assumptions and reflect management **'** **'** s best estimates. We have acquired other companies and intangible assets and may not realize all the economic benefit from those acquisitions, which could cause an impairment of goodwill or intangibles ~~. In preparing the financial statements for the quarter ended September 30, 2022, we identified a triggering event and recorded a $ 1, 187 million non- cash goodwill impairment charge associated with two reporting units within the Technologies & Equipment segment. At December 31, 2022, the remaining goodwill related to the Digital Dental Group and Equipment & Instruments reporting units was $ 235 million and $ 193 million, respectively. As the fair value of these reporting units approximate carrying value as of December 31, 2022, any further decline in key assumptions could result in additional impairment in future periods. In addition, we tested the indefinite- lived intangible assets related to these businesses, along with certain indefinite- lived intangibles related to the Consumables segment, and determined that certain tradenames and trademarks were impaired, resulting in the recording of an impairment charge of $ 94 million for the three months ended September 30, 2022. During the quarter ended December 31, 2022, we identified a triggering event due to reductions of near- term forecasts for specific tradenames and continued adverse macroeconomic factors, including the impact of foreign exchange rates, resulting in the recording of an impairment charge of $ 6 million for the three months ended December 31, 2022. As the fair value of these indefinite- lived intangible assets impaired in the third and fourth quarters approximate carrying value as of December 31, 2022, any further decline in key assumptions could result in additional impairment in future periods. At December 31, 2022, we have $ 455 million in indefinite- lived intangible assets and $ 2. 7 billion of goodwill recorded on our balance sheet~~ . The goodwill and indefinite- lived intangible asset impairment analyses are sensitive to changes in key assumptions used, such as discount rates, revenue growth rates, perpetual revenue growth rates, royalty rates, and operating margin percentages of the business as well as current market conditions affecting the dental and medical device industries in both the **United States** ~~U. S.~~ and globally. Given the uncertainty in the marketplace and other factors affecting management' s assumptions underlying our discounted cash flow model, the assumptions and projections used in the analyses may ~~not be realized~~ **deviate materially from future assumptions and projections** and our current estimates could vary significantly in the future, which may result in an additional goodwill or indefinite- lived intangible asset impairment charge at that time. others,or that the patents will not be successfully challenged or circumvented by third parties,including our competitors.The protective steps that we have taken may be inadequate to deter misappropriation of our proprietary information.We may be unable to detect or protect against the unauthorized use or misappropriation of,or take appropriate steps to enforce,our intellectual property rights.Effective patent,trademark and trade secret protection may not be available in every country in which we will offer,or intend to offer,our products.Any failure to adequately protect our intellectual property ~~rights~~ could devalue our proprietary content and impair our ability to compete effectively.Further,defending our intellectual property rights could result in the expenditure of significant financial and managerial **resources** Our success will depend in part on our ability to obtain ~~and enforce claims in our~~ patents ~~directed to~~ **for technology in** our products **and defend infringement on our patents by third parties that relate to our products** , technologies and processes, both in the **United States** ~~U. S.~~ and in other countries. Risks and uncertainties that we face with respect to our patents and patent applications include the following: • the pending patent applications that we have filed, or to which we have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents; • the allowed claims of any patents that are issued may not provide meaningful protection; • ~~we may be unable to develop additional proprietary technologies that are patentable; • the patents licensed or issued to us may not provide a competitive advantage; •~~ other companies may challenge patents licensed or issued to us; • disputes may arise regarding inventions and corresponding ownership rights in inventions and know- how resulting from the joint creation or use of intellectual property by us and our respective licensors; and • other companies may design around the technologies patented by us. ~~Our profitability could suffer if~~ **From time to time,** third parties **may claim that one or more of our products or services** infringe **their** ~~upon our~~ intellectual property rights ~~or misappropriate our technologies and trademarks for their own businesses~~ . ~~To protect our rights~~ **We analyze and take action in response** to **such claims** ~~our intellectual property, we rely~~ on a **case-** ~~combination of patent and trademark law, trade secret protection, confidentiality agreements and contractual arrangements with our employees, strategic partners and others. We cannot assure you that any of our patents, any of the patents of which we are a licensee or any patents which may be issued to us or which we may license in the future, will provide us with a competitive advantage or afford us protection against infringement~~ by **- case basis** others, or that the patents will..... expenditure of significant financial and managerial resources . Litigation may ~~also~~ be necessary ~~to enforce our intellectual property rights or~~ to defend against any **such** claims of infringement of rights owned by third parties that are asserted against us. In addition, ~~we~~ **it** may ~~have~~ **be necessary** to participate in one or more interference proceedings declared by the U. S. Patent and Trademark Office, the European Patent Office or other foreign patent governing authorities, to determine the priority of inventions, which could result in substantial costs. Acquisitions by us of products **, technologies** or **processes, either through acquisitions of** businesses **or assets,** that are found to infringe upon the intellectual property rights of others and the

resulting changes to the competitive landscape of the industry could further increase this risk. If we become involved in litigation or interference proceedings, we may incur substantial expense, and the proceedings may divert the attention of **key** ~~our technical and management~~ personnel, even if we ultimately prevail ~~. An adverse determination in proceedings of this type could subject us to significant liabilities, allow our competitors to market competitive products without obtaining a license from us, prohibit us from marketing our products or require us to seek licenses from third parties that may not be available on commercially reasonable terms, if at all. If we cannot obtain such licenses, we may be restricted or prevented from commercializing our products~~ . The enforcement, defense and prosecution of intellectual property rights, including the U. S. Patent and Trademark Office' s, the European Patent Office' s and other foreign patent offices' interference proceedings, and related legal and administrative proceedings in the **United States** ~~U. S.~~ and elsewhere, involve complex legal and factual questions. As a result, these proceedings are costly and time- consuming, and their outcome is uncertain. ~~Litigation may be necessary to: • assert against others or defend us against claims of patent or trademark infringement; • enforce patents owned by, or licensed to us from, another party; • protect our trade secrets or know- how; or • determine the enforceability, scope and validity of our proprietary rights or the proprietary rights of others.~~ We utilize ~~the~~ short and long- term debt markets to obtain capital from time to time. Our continued access to sources of liquidity depends on multiple factors, including global economic conditions, the condition of global credit markets, the availability of sufficient amounts of financing, operating performance, and credit ratings. Macroeconomic **impacts, including natural disasters, pandemics, geopolitical** conditions **or** ~~, such as the~~ **other catastrophic events** ~~COVID- 19 pandemic~~ , may result in significant disruption in the credit markets, which may adversely affect our ability to refinance existing debt or obtain additional financing to support operations or to fund new acquisitions or capital- intensive internal initiatives. Any adverse changes in our credit ratings may result in increased borrowing costs for future long- term debt or short- term borrowing facilities which may in turn limit financing options, including access to the unsecured borrowing market. There is no guarantee that additional debt financing will be available in the future to fund obligations, or that it will be available on commercially reasonable terms, in which case we may need to seek other sources of funding. In addition, the terms of future debt agreements could include additional restrictive covenants that would reduce flexibility. We have debt securities outstanding of approximately $ 1. ~~8~~ **9** billion **as of December 31, 2023** . We also **can** ~~have the ability to~~ incur up to $ 700 million of indebtedness under the **multi- currency** revolving credit facility (" ~~2018~~ **2023** Credit Facility "), as discussed below, and may incur significantly more indebtedness in the future. Our current debt agreements contain a number of covenants and financial ratios, which we are required to satisfy. Under the Note Purchase Agreement dated December 11, 2015, we are required to maintain ratios of debt outstanding to total capital not to exceed the ratio of 0. 6 to 1. 0, and operating income excluding depreciation and amortization to interest expense of not less than 3. 0 times, in each case, as such terms are defined in the Note Purchase Agreement. Many of our subsequent private outstanding debt agreements have been amended to reflect these covenants. We may need to reduce the amount of our indebtedness outstanding from time to time ~~in order~~ to comply with such ratios, though no assurance can be given that we will be able to do so. Our failure to maintain such ratios or a breach of the other covenants under our debt agreements outstanding from time to time could result in an event of default under the applicable agreement. Such a default may allow the creditors to accelerate the related indebtedness and may result in the acceleration of any other indebtedness. Any future violations of the covenants under our debt agreements may hurt our reputation and credibility with our stockholders and our debt holders and may compromise our future ability to finance our operations through the public equity or debt markets. Breach of covenants could have additional negative consequences including, but not limited to the following: • **increased** ~~making it more difficult~~ **difficulty** ~~for us~~ to satisfy our obligations with respect to our indebtedness; • requiring us to dedicate significant cash flow from operations to the ~~payment~~ **repayment** of principal and interest **payments** on our indebtedness, which would reduce the funds we have available for other purposes, including working capital, capital expenditures, ~~R & D~~ **research and development, dividends, share repurchases** and acquisitions; and • reducing our flexibility in planning for or reacting to changes in our business and market conditions. ~~Even absent a breach of covenants, there~~ **There** is no guarantee that we will be able to renew or replace our existing debt agreements as they become due, including ~~the 2018 Credit Facility~~ **debt instruments with principal of $ 74 million** maturing in **October** 2024, which would harm our overall liquidity. Our ability to make payments on our indebtedness and contractual obligations, and to fund our operations depends on our future performance and financial results, which, to a certain extent, are subject to general economic, financial, competitive, regulatory and other factors and the interest rate environment that are beyond our control. Although management believes that we have and will continue to have sufficient liquidity, there can be no assurance that our business will generate sufficient cash flow from operations in the future to service our debt, pay our contractual obligations and operate our business. ~~Our~~ **Due to the global nature of our business, movements in** foreign ~~currency hedging~~ **exchange rates may impact our consolidated statements of operations, consolidated balance sheets** and cash ~~management transactions~~ **flows. With approximately two- thirds of our sales located outside the United States, our consolidated net sales are impacted negatively by the strengthening or positively by the weakening of the U. S. dollar as compared to certain foreign currencies. Additionally, movements in certain foreign exchange rates** may **impact our results of operations, financial condition and liquidity since a number of our manufacturing and distribution operations are located outside of the United States. Although we currently use and may in the future use certain financial instruments to attempt to mitigate market fluctuations in foreign exchange rates, there can** be **no assurance that such measures will be** ~~ineffective~~ -- **effective, available through financial markets** or **that** ~~only partially mitigate the~~ **they will not** ~~impact of exchange rate~~ **create fluctuations, exposing additional financial obligations for** us ~~to unexpected interest rate volatility~~ . **We** ~~As part of our risk management program, we~~ use foreign currency exchange forward contracts ~~. While intended~~ to reduce the effects of exchange rate fluctuations, **which** ~~these transactions~~ may limit our potential gains or expose us to ~~loss~~ **losses** . Should our counterparties to such transactions or the sponsors of the exchanges through which these transactions are offered fail to honor their obligations due to financial distress or otherwise, we would be exposed to potential losses or the inability to recover

anticipated gains from these transactions. We enter into foreign currency exchange forward contracts as economic hedges of trade commitments or anticipated commitments denominated in currencies other than the functional currency to mitigate the effects of changes in currency rates. Although we do not enter into these instruments for trading purposes or speculation, and although our management believes all of these instruments are economically effective for accounting purposes as hedges of underlying physical transactions, these foreign exchange commitments are dependent on timely performance by our counterparties. Their failure to perform could result in us having to close these hedges without the anticipated underlying transaction and could result in losses if foreign currency exchange rates have changed. We enter into interest rate swap agreements from time to time to manage some of our exposure to interest rate volatility. These swap agreements involve risks, such as the risk that counterparties may fail to honor their obligations under these arrangements. In addition, these arrangements may not be effective in reducing our exposure to changes in interest rates. If such events occur, our results of operations may be adversely affected. Most of our cash deposited with banks is not insured and would be subject to the risk of bank failure. Our total liquidity also depends in part on the availability of funds under our ~~2018~~ **2023** Credit Facility. The failure of any bank in which we deposit our funds or that is part of our ~~2018~~ **2023** Credit Facility could reduce the amount of cash we have available for operations and additional investments in our business. RISKS RELATED TO OUR ~~INTERNATIONAL~~ **GLOBAL** OPERATIONS Approximately two- thirds of our sales are ~~located~~ in regions outside the **United States** ~~U. S~~. In addition, we anticipate that sales outside of the **United States** ~~U. S.~~ will continue to expand and account for a significant portion of our revenue. Operating internationally is subject to ~~a number of~~ uncertainties, including, but not limited to, the following: • economic and political instability; • import or export licensing requirements; • additional compliance- related risks; • trade restrictions and tariffs; • product registration requirements; • longer payment cycles; • changes in regulatory requirements and tariffs, including recent restrictions in China on the proportion of certain medical equipment which can be imported; • potentially adverse tax consequences; and • trade policy changes **. Changes in or the imposition of tariffs could make it more difficult or costly for us to export our products to other countries. These measures could also result in increased costs for goods imported into the United States. This in turn could require us to increase prices to our customers which may reduce demand, or, if we are unable to increase prices, result in lowering our margin on products sold. We cannot predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers and our suppliers, which in turn could adversely impact our business, financial condition and results of operations.** Specifically, the Chinese government has implemented a volume- based procurement process designed to decrease prices for medical devices and other products, which has in the past resulted in, and could in the future result in, reduced margins on covered devices and products, required renegotiation of distributor arrangements, **or** an incurrence of inventory- related charges. For further information, please see Part 1. Item 1, ~~"~~ **“** Business- Regulation. ~~"~~ **”** As a result of such program, which **took** ~~is anticipated to take~~ effect in the first half of 2023, the Company ~~expects that~~ **experienced a temporary reduction in net** sales of ~~our Implants~~ - **implant** products in China ~~will be negatively affected by~~ **, in part due to** price reductions **, which was offset** ~~. Sales in China have also been negatively affected~~ by ~~purchasing behavior~~ **higher net sales volumes** in ~~anticipation of government regulations which will require certain amounts of medical equipment purchased by state enterprises to be sourced locally. Additionally, changes in or the imposition of tariffs could make it more difficult or costly for us to export our products to other~~ -- **the second half of 2023** ~~countries. These measures could also result in increased costs for goods imported into the U. S. This in turn could require us to increase prices to our customers which may reduce demand, or, if we are unable to increase prices, result in lowering our margin on products sold~~ . We cannot predict future ~~trade policy~~ **impacts of the volume- based procurement program on** ~~or~~ **our** ~~the terms of~~ **business, including** any ~~renegotiated trade agreements and their impact on our business. The adoption and~~ expansion of ~~trade restrictions, the occurrence of a trade war, or other~~ -- **the program** ~~governmental action related~~ to **include additional** ~~tariffs or trade agreements or policies has the potential to adversely impact demand for our~~ products ~~,~~ **within** our **portfolio** ~~costs, our customers and our suppliers, which in turn could adversely impact our business, financial condition and results of operations~~ . Certain of these risks may be heightened **because** ~~as a result~~ of changing political climates which may lead to changes in areas such as trade restrictions and tariffs, regulatory requirements and exchange rate fluctuations, which may adversely affect our business and financial performance. For example, **due to** ~~as a result of~~ escalating tensions and the subsequent invasion of Ukraine by Russia, the **United States** ~~U. S.~~, other North Atlantic Treaty Organization member states, the EU and other countries have imposed sanctions on Russia, including its major financial institutions and certain other businesses and individuals, Belarus, the Crimea Region of Ukraine, the so- called Donetsk People’ s Republic and the so- called Luhansk People’ s Republic. Russia also imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia, imposed various restrictions on transacting with non- Russian parties, banned exports of various products, and imposed other economic and financial restrictions. These include restrictions on the ability of companies to repatriate or otherwise remit cash from their Russian- based operations to locations outside of Russia. Russia may further respond in kind, and the continuation of the conflict may result in additional sanctions being enacted by the **United States** ~~U. S.~~, other North Atlantic Treaty Organization member states, the EU or other countries. The length, impact, and outcome of this ongoing military conflict is highly unpredictable and could lead to significant market and other disruptions, which, along with the spillover effect of ongoing civil, political and economic disturbances on surrounding areas, may significantly devalue currencies utilized by us or have other adverse impacts including increased costs of raw materials and inputs, manufacturing or shipping delays or increases in inflation rate, **cyberattacks** ~~cyber attacks~~ and supply chain challenges. Export controls implemented as part of sanctions could also restrict the sale of equipment or products containing U. S. developed software and technology into Russia. For the year ended December 31, ~~2022~~ **2023** , net sales in Russia and Ukraine were approximately ~~3~~ **2** % of our consolidated net sales, and net assets in these countries were $ ~~83~~ **78** million ~~as of December~~

~~31, 2022~~ . These net assets include $ ~~71~~ **42** million of cash and cash equivalents ~~, which~~ **held within Russia** as ~~a result~~ of **December 31, 2023. Due to** ~~current~~ **currency** control measures **imposed** by the Russian government **, which include restrictions on the ability of companies to repatriate or otherwise remit cash from their Russian- based operations to locations outside of Russia,** we ~~are~~ **may be** limited in our ability to transfer **this cash balance** out of Russia without incurring substantial costs, if at all. The **recent terrorist attacks by Hamas militants crossing the border from Gaza to Israel in October 2023 and the subsequent military response by the Israeli government has resulted in significant unrest and uncertainty within that region, including the possibility that escalating violence and involvement of other terrorist groups from neighboring countries may further impact our employees and operations. The Company' s operations in Israel consist of two manufacturing facilities for implants products, with one site in northern Israel and one in southern Israel, and combined they employ approximately 300 associates. These facilities remain open and continue to operate. We may, however, determine to discontinue production for the safety of our employees, or we could face future production slowdowns or interruptions at either location due to the impacts of the war including personnel absences as several of our employees were called to active military duty, or due to other resource constraints such as the inability to source materials for production. For the year ended December 31, 2023, net sales of products manufactured at these sites comprised approximately 3 % of our consolidated net sales and 13 % of the net sales attributed to our Orthodontic and Implant Solutions segment. Net assets within Israel totaled $ 197 million as of December 31, 2023, consisting primarily of acquired technology, cash, inventory, and property, plant and equipment associated our operations in country. The** full impact of these events on economic conditions in ~~the~~ **these** ~~region~~ **regions** is currently unknown and could have a material adverse effect on our results of operations, cash flows or financial condition. ~~Due to~~ **Additionally,** ~~the~~ **other** ~~international nature~~ **events such as the outbreak** of **a global pandemic, including new variants of COVID- 19, or other adverse public health developments could materially affect** our business ~~, movements~~ in ~~foreign exchange rates may impact our consolidated statements of operations, consolidated balance sheets and cash flows. With approximately two- thirds of our sales located outside the U. S., our consolidated net sales are impacted negatively by the strengthening or positively by the weakening of the U. S. dollar as compared to certain foreign currencies. Additionally, movements in certain foreign exchange rates may unfavorably or favorably impact our results of operations, financial condition and liquidity as~~ a number of **ways, including reduced demand for our products in certain regions** ~~our~~ **or** ~~manufacturing and distribution operations are located outside of~~ **our inability to timely meet our customer' s orders,** the ~~U. S. Although~~ **failure of third parties on which** we ~~currently~~ **rely, including our suppliers, customers, contractors, commercial banks, transportation service providers and external business partners, to meet their respective obligations to** ~~use~~ **us** ~~and may~~ **, or significant disruptions** in ~~the~~ **their** ~~future use ability to do so and certain~~ **uncertainty in the global** financial ~~instruments to attempt to mitigate market~~ **markets** ~~fluctuations in foreign exchange rates, there can be no assurance that such measures will be effective or that they will not create additional financial obligations for us~~ . RISKS RELATED TO OUR REGULATORY ENVIRONMENTS As a company with ~~international~~ **global** operations, we are subject to income taxes, as well as non- income- based taxes, in the **United States** ~~U. S.~~ and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable at the time made, the actual outcome could differ from the amounts recorded in our financial statements (and such differences may be material). If the IRS ~~,~~ or other tax authorities, disagree with the positions we take, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, and changes in interpretations of tax laws. Due to economic and political conditions, tax rates in various jurisdictions may be subject to significant change and could materially impact our effective tax rate. Our corporate structure is intended to enhance our operational and financial efficiency and increase our overall profitability. The tax authorities of the countries in which we operate may challenge our methodologies for transfer pricing or change the way in which certain transactions are taxed which could **materially** increase our effective tax rate ~~(and such increase may be material)~~ . In addition, certain governments are considering, and may adopt, tax reform measures that could significantly increase our worldwide tax liabilities. The Organization for Economic Co- operation and Development **(" OECD ")** and other government bodies have focused on issues related to the taxation of **multi-** ~~multinational~~ ~~-----~~ **national** corporations, including ~~,~~ in the area of " base erosion and profit shifting, " where payments are made from affiliates in jurisdictions with high tax rates to affiliates in jurisdictions with lower tax rates. Some of these proposals include a two- pillar approach to global taxation, focusing on global profit allocation and a global minimum tax rate (" Pillar Two "). On December 12, 2022, the European Union member states agreed to implement the OECD' s global corporate minimum tax rate of 15 %, to be effective as of January 2024. Other countries **have made, or** are ~~also~~ actively considering **,** changes to their tax laws to adopt certain parts of the OECD' s proposals. ~~In December 2022, South Korea enacted new~~ **Due to the large scale of our U. S. and** global **business activities, the** ~~minimum tax rules to align with Pillar Two. The~~ enactment of Pillar Two legislation ~~in other countries~~ could **increase tax uncertainty and could also** have a material effect on the Company ~~'~~ **'** s effective tax rate, financial position, results of operations, and cash flows. The Company will continue to monitor and reflect the impact of such legislative changes in future financial statements as appropriate. We must obtain certain approvals ~~by,~~ and marketing clearances from, governmental authorities, including the FDA and similar health authorities in foreign countries to market and sell ~~our~~ select products in those countries. These agencies regulate the marketing, manufacturing, labeling, packaging, advertising, ~~sale~~ **sales** and distribution of medical devices. The FDA enforces additional regulations regarding the safety of X- ray emitting devices ~~.~~ ~~Our products are currently regulated by such authorities and our new products require approval by, or marketing clearance from, various governmental authorities, including the FDA~~ . Various U. S. states also impose manufacturing, licensing, and distribution regulations. The FDA review process typically requires extended proceedings pertaining to the safety and efficacy of new products. A 510 (k) application is required ~~in order~~ to market certain classes of new or modified medical devices. If

specifically required by the FDA, a pre- market approval, or PMA, may be necessary. Such proceedings, which must be completed prior to marketing a new medical device, are potentially expensive and time consuming. They may delay or hinder a product' s timely entry into the marketplace. Moreover, there can be no assurance that the review or approval process for these products by the FDA or any other applicable governmental authority will occur in a timely fashion, if at all, or that additional regulations will not be adopted or current regulations amended in such a manner as will adversely affect us. The FDA also oversees the content of advertising and marketing materials relating to medical devices which have received FDA clearance. Failure to comply with the FDA' s advertising guidelines may result in the imposition of penalties. We are also subject to other federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted and inadequate employee training for critical compliance and regulatory requirements may result in the failure to adhere to applicable laws, rules and regulations. Similar to the FDA review process, the EU review process typically requires extended proceedings pertaining to the safety and efficacy of new products. Such proceedings, which must be completed prior to marketing a new medical device, are potentially expensive and time consuming and may delay or prevent a product' s entry into the marketplace. Our products that fall into the category of Class I as classified by **the** EU MDD were mandated to be certified under the new EU MDR. These regulations ~~as well~~ applied to all medical device manufacturers who market their medical devices in **the** EU and ~~all had~~ **manufacturers were required** to perform significant upgrades to quality systems and processes including technical documentation and **obtain** ~~subject them to~~ new certification under **the** EU MDR ~~in order~~ to continue to sell those products in the EU. Although all medical device manufacturers were required to certify their Class I products by May 2021, the EU MDR regulations for additional Classes of medical devices ~~is~~ **are** mandated to be fully ~~enforceable~~ **enforced** by May 2024. This also includes completion of certified quality management systems to manufacturers quality management systems **. On January 6, 2023, the EU Commission submitted a proposed amendment to extend the MDR transitional periods until December 31, 2027 for higher risk devices and December 31, 2028, for other medical devices to ensure continued access to medical devices for patients and to allow medical devices already placed on the market in accordance with the current legal framework to remain on the market** . We remain focused on ensuring that all our products that are considered to be medical ~~device~~ **devices** will be fully certified as required by the EU MDR **deadlines** ~~dates and timelines~~ . Additionally, the UK has negotiated an exit from the EU, (commonly referred to as Brexit) and, as a result, the EU CE marking will be recognized in the UK through **the earlier of the expiration of the product' s CE certificate or** June ~~2023~~ **2028** . **After which** ~~Following June 2023~~ , the UK may impose its own differing regulatory requirements for products being imported from the EU into the UK. Failure to comply with these rules, regulations, self- regulatory codes, circulars and orders could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse impact on our business. Also, these regulations may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private regulators could result in reputational harm and the incurring of substantial costs. In addition, many of these laws are vague or indefinite and have not been interpreted by the courts ~~,~~ and have been subject to frequent modification and varied interpretation by prosecutorial ~~,~~ **or** regulatory authorities, increasing compliance risks. ~~Inadequate levels of reimbursement from governmental or~~ **Some state legislatures have passed legislation and** other ~~third-~~ **state legislatures have proposed legislation designed to preclude or significantly limit teledentistry. Furthermore, our ability to conduct business in each state is dependent, in** ~~party-~~ **part** ~~payors~~ **, upon that particular state' s treatment of remote healthcare and that state dental board' s regulation of the practice of dentistry, each of which is subject to changing political, regulatory, and other influences. Some state dental boards established rules in a manner that purports to limit** ~~for-~~ **or** ~~procedures using~~ **restrict our ability to conduct our business as currently conducted. It is possible that the laws, rules and regulations governing the practice of dentistry and orthodontics in one** ~~our-~~ **or** ~~products~~ **more states** may ~~cause~~ **change** ~~our-~~ **or** ~~revenue~~ **be interpreted in a manner unfavorable** to ~~decline~~ **our business. If adverse laws or regulations are adopted or any such claims are successful, and we were unable to adapt our business model accordingly, our operations in such states would be disrupted, which could have a material adverse effect on our business, financial condition, and results of operations** . Third- party payors, including government health administration authorities, private health care insurers and other organizations **,** regulate the reimbursement of fees related to certain diagnostic procedures or medical treatments. Third- party payors are increasingly challenging the price and cost- effectiveness of medical products and services. While we cannot predict what effect the policies of government entities and other third- party payors will have on future sales of our products, there can be no assurance that such policies would not cause our revenue to decline. We manufacture and sell a wide portfolio of dental and medical device products. While we endeavor to ensure that our products are safe and effective, there can be no assurance that there may not be challenges from time to time regarding the real or perceived quality, health or environmental impact of our products or certain raw material components of our products. We manufacture and sell dental filling materials that may contain bisphenol- A, commonly called BPA. BPA is found in many everyday items, such as plastic bottles, foods, detergents and toys, and may be found in certain dental composite materials or sealants either as a by- product of other ingredients that have degraded, or as a trace material left over from the manufacture of other ingredients used in such composites or sealants. The FDA currently allows the use of BPA in dental materials, medical devices, and food packaging. Nevertheless, public reports and concerns regarding the potential hazards of BPA could contribute to a perceived safety risk for our products that contain mercury or BPA. Adverse publicity about the quality or safety of our products, whether or not ultimately based on fact, may have an adverse effect on our brand, reputation and operating results and legal and regulatory developments in this area may lead to litigation and / or product limitations or discontinuation. We are subject to federal, state, local and foreign laws, rules, regulations, self- regulatory codes, circulars and orders relating to health care fraud, including, but not limited to, the U. S.

Federal Anti- Kickback Statute, the UK Bribery Act 2010 (c. 23), Brazil' s Clean Company Act 2014 (Law No. 12, 846) and China' s National Health and Family Planning Commission (" NHFPC ") circulars No. 49 and No. 50. Some of these laws, referred to as " false claims laws, " prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payors and programs. Other laws, referred to as " anti- kickback laws, " prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for or recommending ordering, purchasing or leasing, of items or services that are paid for by federal, state and other health care payors and programs. The U. S. government has expressed concerns about financial relationships between suppliers ~~on the one hand~~ and physicians and dentists ~~on the other~~. As a result, we regularly review and revise our marketing practices as necessary to facilitate compliance. In addition, under the reporting and disclosure obligations of the U. S. Physician Payment Sunshine Act and similar foreign laws, rules, regulations, self- regulatory codes, circulars and orders, such as France' s Loi Bertrand and rules issued by Denmark' s Health and Medicines Authority, the general public and government officials will be provided with access to detailed information with regard to payments or other transfers of value to certain practitioners (including physicians, dentists and teaching hospitals) by applicable drug and device manufacturers subject to such reporting and disclosure obligations, which includes us. This information may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Failure to comply with health care fraud laws, rules, regulations, self- regulatory codes, circulars and orders could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse impact on our business. Also, these laws may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. In addition, many of these laws are vague or indefinite and have not been interpreted by the courts, and have been subject to frequent modification and varied interpretation by prosecutorial ~~,~~ **and** regulatory authorities, increasing compliance risks. We cannot predict whether changes in applicable laws, rules, regulations, self- regulatory codes, circulars and orders, or the interpretation thereof, or changes in our services or marketing practices in response, could adversely affect our business. We are subject to extensive domestic and foreign laws, rules, regulations, self- regulatory codes, circulars and orders which are administered by various international, federal and state governmental authorities, including, among others, the FDA, the Office of Foreign Assets Control of the U. S. Department of the Treasury (" OFAC "), the Bureau of Industry and Security of the U. S. Department of Commerce (" BIS "), the U. S. Federal Trade Commission, the U. S. Department of Justice, the Environmental Protection Agency (" EPA "), and other similar domestic and foreign authorities. These laws, rules, regulations, self- regulatory codes, circulars and orders include, but are not limited to, the U. S. Food, Drug and Cosmetic Act, the **EU** ~~European Council Directive 93 / 42 / EEC on Medical Devices (" MDD ") (1993)~~ (and implementing and local measures adopted thereunder), the Federal Health Information Technology for Economic and Clinical Health Act (" HITECH Act "), the Federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), France' s Data Protection Act of 1978 (rev. 2004), the U. S. Foreign Corrupt Practices Act (the " FCPA "), the U. S. Federal Anti- Kickback Statute and similar international anti- bribery and anti- corruption laws, the Physician Payments Sunshine Act, regulations concerning the supply of conflict minerals, various environmental regulations such as the Federal Water Pollution Control Act (the " Clean Water Act "), the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the " Health Care Reform Law "), and regulations relating to trade, import and export controls and economic sanctions. Such laws, rules, regulations, self- regulatory codes, circulars and orders are complex and are subject to change. The FCPA generally prohibits companies and their affiliates from making improper payment to non- U. S. officials for the purpose of obtaining or retaining business, and also includes certain books and records and internal accounting controls requirements. Our internal policies, procedures and Code of Ethics and Business Conduct mandate compliance with these anti- corruption laws. However, we operate in some countries known to experience corruption. Despite our training and compliance programs, we cannot provide assurance that our internal policies and procedures will always protect us from violation of such anti- corruption laws committed by our **employees or** affiliated entities or their respective officers, directors, employees and agents. **Failure to comply** ~~If we are not in compliance~~ with the FCPA and other laws governing the conduct of business with government entities (including local laws), **will** ~~we may be~~ subject **us** to criminal and civil penalties and other remedial measures, which could have a material adverse impact on our business, financial condition, results of operations and liquidity. Any ongoing investigation of any potential violations of the FCPA or other anti- corruption laws by the U. S. or foreign authorities could harm our reputation and have an adverse impact on our business, financial condition and results of operations. On December 31, 2020, we acquired Byte, a leading provider in the direct- to- consumer, doctor- directed aligner market. Byte' s business in the **United States** ~~U. S.~~ is subject to various state laws, rules and policies which govern the practice of dentistry within such state. Byte contracts with an expansive nationwide network of independent licensed dentists and orthodontists for the provision of clinical services, ~~including~~ **which includes** the oversight and control of each customer' s clinical treatment; however, there can be no assurance that such business model will not be challenged as the corporate practice of dentistry by state governmental authorities, trade associations, or others. Additionally, future legislative or regulatory changes within such states may have a negative impact on Byte' s business model. Compliance with the numerous applicable existing and new laws, rules, regulations, self- regulatory codes, circulars and orders could require us to incur substantial regulatory compliance costs. There can be no assurance that governmental authorities will not raise compliance concerns or perform audits to confirm compliance with such laws, rules, regulations, self- regulatory codes, circulars and orders. For example, most of our products are classified as medical devices or pharmaceuticals **,** which are subject to extensive regulations promulgated by the U. S. federal government, state governments and comparable regulatory agencies in other countries, including the requirement to obtain licenses for the manufacture or distribution of such products. Failure to comply with applicable laws, rules, regulations, self- regulatory codes, circulars or orders could result in a range of

governmental enforcement actions, including fines or penalties, injunctions and / or criminal or other civil proceedings. Any such actions could result in higher than anticipated costs or lower than anticipated revenue and could have a material adverse effect on our reputation, business, financial condition and results of operations. RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK We experience significant fluctuations in quarterly sales and earnings due to **several** ~~a number of~~ factors, some of which are substantially outside of our control, including but not limited to: • general economic conditions, as well as those specific to the healthcare industry and related industries; • changes in income tax laws and incentives that could create adverse tax consequences; • the execution of restructuring plans; • the complexity of our organization; • our ability to supply products to meet customer demand; • the timing of new product introductions by us and our competitors; • the timing of industry trade shows; • changes in customer inventory levels; • developments in government or third party payor reimbursement policies; • changes in customer preferences and product mix; • fluctuations in manufacturing costs; • competitors' sales promotions; **and** • fluctuations in currency exchange rates ~~; and • the impact of COVID- 19~~ . As a result, we may fail to meet the expectations of investors and securities analysts, which could cause our stock price to decline. Certain provisions of our Certificate of Incorporation and By- laws and of Delaware law could have the effect of making it difficult for a third party to acquire a controlling interest in us. Such provisions include, among others, a provision allowing the Board of Directors to issue preferred stock having rights senior to those of the common stock and certain requirements which make it difficult for stockholders to amend our By- laws and prevent them from calling special meetings of stockholders. Delaware law imposes some restrictions on mergers and other business combinations between us and any " interested stockholder " with beneficial ownership of 15 % or more of our outstanding common stock. GENERAL RISKS Our ~~revenue, results of operations, cash flow and liquidity may be materially adversely impacted by the ongoing COVID- 19 outbreak. We continue to closely monitor the global impacts of the COVID- 19 pandemic. The COVID- 19 pandemic has negatively impacted business and healthcare activity globally and has created significant volatility, uncertainty and economic disruption in the U. S. and international markets and within the markets in which we operate. The pandemic has adversely affected and is likely to further adversely affect nearly all aspects of our business and markets, including our sales, operations, cash flow and workforce and the operations of our customers, suppliers, vendors and business partners. Specifically, authorities in China periodically re- imposed severe restrictions on individual and business activities during 2022, resulting in a loss of sales due to distribution constraints and lower demand from reduced patient traffic locally. Although certain of these restrictions were lifted late in the year, this also coincided with resurgence of COVID- 19 infections from variants of the virus. Adverse trends in certain regions and particularly China could persist if these restrictions are renewed as a result of additional outbreaks. More generally, the impact of the pandemic may increase the possibility of uncertainty in the global financial markets, high inflation and extended economic downturn, which could reduce our ability to incur debt or access capital and impact our results and financial condition even after local conditions improve. There are no assurances that the credit markets or the capital markets will be available to us in the future or that the lenders participating in our credit facilities will be able to provide financing in accordance with their contractual obligations. We do not yet know the full extent of the ultimate impact of the continued COVID- 19 pandemic on our business, operations, or the global economy. The extent of such impact will depend on future developments, including the severity and frequency of any future COVID- 19 variants and related outbreaks, and actions taken to address the impacts, among others. Even after the COVID- 19 pandemic has subsided, we may continue to experience materially adverse effects on our results of operations and financial condition. To the extent that the COVID- 19 outbreak continues to adversely affect the business and financial performance, it could also heighten many of the other risks described in this report. Our~~ business, operating results, financial condition and liquidity may be adversely affected by changes in global economic conditions including inflation, supply chain disruptions **,** credit market conditions, levels of consumer and business confidence, and other factors that are generally beyond our control. The current global supply chain and labor market challenges and inflationary pressures have negatively affected, and we expect will continue to negatively affect, our results of operations. Specifically, the Company ~~has recently~~ **continues to** ~~experienced~~ **experience** higher prices and supply chain ~~disruption~~ **disruptions** for certain of our raw materials, particularly for electronic components ~~used in our products~~ **, as well as wage inflation for direct labor** . As it pertains to demand for our products, certain dental specialty products and dental equipment and related products that support discretionary dental procedures, especially elective procedures in implants and aligners, may also be susceptible to unfavorable changes in economic conditions. Decreases in consumer discretionary spending could negatively affect our business and result in a decline in sales and financial performance. Additionally, interest rate increases have created financial market volatility which could further negatively impact financial markets, lead to an economic downturn or recession, and tighten availability of, and increase the costs of capital for the Company. These and any other unfavorable economic conditions could increase our funding costs, limit our access to the capital markets or result in a decision by lenders not to extend credit to us. Tightening of credit in financial markets **has** also ~~could~~ adversely ~~affect the~~ **impacted our customers' and suppliers'** ability ~~of our customers and suppliers~~ to obtain financing for significant purchases and operations ~~,~~ **with acceptable terms and** could result in **additional or worsening impacts in the future, including** a decrease in or cancellation of orders for our products and services, ~~could impact the ability~~ **inability** of our customers to make payments, and ~~could increase~~ **increased** ~~the~~ risk of supplier financial distress. The Company has sought to offset the elevated costs resulting from raw material cost inflation with annual price increases but has been only partially successful. Should the higher inflationary environment continue, we may not be able to increase the prices of our offerings sufficiently to keep up with the rate of inflation. Any of the above factors could individually or in combination have a material adverse effect on our operating results, financial condition and liquidity. ~~On April 11, 2022, we announced that our Executive Vice President, Chief Financial Officer resigned from his position effective May 6, 2022. Additionally, on April 19, 2022, we announced that we terminated our Chief Executive Officer, effective immediately. The Board of Directors appointed an Interim Chief Executive Officer, effective as of April 19, 2022, and Interim Chief Financial Officer which became effective on May 6, 2022. On August 25th, we announced the appointment of our new Chief Executive Officer, which became effective on~~

~~September 12, 2022, and on September 22, 2022, we announced the appointment of our new Chief Financial Officer, which became effective on September 26, 2022. These leadership transitions along with other senior management changes may be inherently difficult to manage and cause operational and administrative inefficiencies, added costs, decreased employee morale, uncertainty and decreased productivity among our employees, increased likelihood of turnover, and the loss of personnel with deep institutional knowledge, which could result in significant disruptions to our operations. In addition, we must successfully integrate the new management team members within our organization in order to achieve our operating objectives, and changes in key management positions may temporarily affect our financial performance and results of operations as new management becomes familiar with our business. These changes could also increase the volatility of our stock price. If we are unable to mitigate these or other similar risks, our business, results of operations and financial condition may be adversely affected.~~ Our success is dependent on our ability to successfully manage our human capital through talent acquisition, engagement, development, and retention. To achieve our strategic initiatives, we need to attract, manage, and retain employees with the right skills, competencies and experiences to **execute our strategy and** support the growth of the business ~~and the~~ **. The** failure to attract and retain such employees to fill key roles may adversely affect our business performance, competitive position and future prospects. We also must retain a pipeline of team members to provide for continuity of succession for senior executive positions. **To** ~~In order to~~ attract and retain qualified employees, we must offer competitive compensation and **benefits and** effectively manage employee performance and development. ~~The recent leadership~~ **Leadership** transitions **or** ~~along with~~ other senior management changes may adversely affect our ability to attract and retain talent. Our inability to attract and retain talent may negatively impact business continuity, new product launches, and innovation initiatives. Further, such organizational challenges may make it difficult to maintain our culture, resulting in employees not adhering to the desired values of the organization. We face the **inherent** risk of **legal actions or claims, including** purported securities class actions, investigations by governmental agencies, product liability **claims, product recall actions, antitrust suits, customs proceedings, tax actions, commercial or contractual claims, employee benefit or discrimination lawsuits, actions based in environmental laws,** and other ~~types~~ **matters. These actions or claims, regardless of their factual bases, might result in substantial costs, restrictions, or otherwise materially injure our business by harming our reputation or distracting our officers, management, and employees. The penalties imposed as a result** of legal actions or claims ~~,~~ **might** ~~including~~ **include** ~~possible~~ **fines, civil penalties, criminal penalties, injunctions,** ~~recall~~ **recalls , and other** ~~actions~~ **sanctions** ~~affecting~~ **that may materially harm our business by reducing our ability to sell or promote** our products **or reducing our profits** . We have insurance policies, including directors' and officers' insurance and product liability insurance, covering these risks in amounts that are considered adequate; however, we cannot provide assurance that the maintained coverage is sufficient to cover future claims or that the coverage will be available in adequate amounts or at a reasonable cost. Also, other types of claims asserted against us may not be covered by insurance. A successful claim brought against us in excess of available insurance, or another type of claim which is uninsured or that results in significant adverse publicity against us, could harm our business and our overall cash flows. **Additionally** ~~Various parties~~ , ~~including us, own and maintain patents and other intellectual property rights applicable to the dental and medical device fields. Although~~ we **include** ~~believe that we operate in a manner that does not infringe upon any third- party intellectual property rights, it is possible that a party could assert that one or more of our products infringe upon such party' s intellectual property and force us to pay damages and / or discontinue the sale of certain products. Additionally, we generally warrant~~ **warranties on select** ~~each of our~~ products against defects in materials and workmanship **, which are generally** for a period of one year from the date of shipment or installation plus any extended warranty period purchased by the customer. The future costs associated with providing product warranties could be material. Successful product warranty claims brought against us could reduce our profits and / or impair our financial condition ~~,~~ and damage our reputation. We ~~operate~~ **have sales or operations** in more than 150 countries and our suppliers' manufacturing facilities are ~~located~~ in multiple locations around the world. While we seek to mitigate our ~~business~~ risks associated with climate events, we recognize that there are inherent climate- related risks regardless of where we conduct our businesses. Global climate change is expected to result in certain types of natural disasters occurring more frequently or with more intense effects. Any natural disaster, power outages or other climate events in such a location or the increased frequency of extreme weather could disrupt the production and distribution of our products in these locations. Current or future insurance arrangements may not provide protection for costs that may arise from such events, particularly if such events are catastrophic in nature or occur in combination. Accordingly, a natural disaster has the potential to disrupt our and our ~~clients~~ **customers** ' businesses and may cause us to experience work stoppages, project delays, financial losses and additional costs to resume operations, including increased insurance costs or loss of cover, legal liability and reputational losses. Increasing natural disasters in connection with climate change could also impact our third- party vendors, service providers or other stakeholders, including disruptions in supply chains, ~~or~~ information technology or other necessary services for our Company. Many governments, regulators, investors, employees, customers and other stakeholders are increasingly focused on environmental, social and governance considerations **(" ESG ")** relating to businesses, including climate change and greenhouse gas emissions, human and civil rights, and diversity, equity and inclusion. ~~In~~ **The increased emphasis on ESG matters has resulted in, and may continue to result in, the adoption of laws and regulations, including** ~~addition~~ **additional reporting requirements** , ~~we~~ **leading to increased compliance costs, as well as increased scrutiny regarding our ESG activities and disclosures, which may lead to increased litigation risks. We** make statements about our **ESG** ~~environmental, social and governance~~ goals and initiatives through our Sustainability Report, our other non- financial reports, information provided on our website, press statements and other communications. **Many of the statements in those voluntary disclosures are based on hypothetical expectations, assumptions, and predictions that may or may not be representative of current or actual risks or events or forecasts of expected risks or events, including the costs associated therewith. Such expectations, assumptions, and predictions are uncertain and may be prone to error or subject to misinterpretation given the long timelines involved and the lack of an**

established single approach to identifying, measuring and reporting on many ESG matters. Responding to these **ESG** ~~environmental, social and governance~~ considerations and implementation of these goals and initiatives involves risks and uncertainties, may require investments, and depends in part on third- party performance or data that is outside our control **which we have not independently verified or which cannot be independently verified** . ~~We~~ **Our selected disclosure framework may need to be changed from time to time due to evolving standards and practices, which may result in a lack of consistent or meaningful comparative data from period to period. In addition, our interpretation of reporting frameworks or standards may differ from those of others and such frameworks or standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals. Further, we** cannot guarantee that we will achieve our **ESG** ~~announced sustainability~~ goals and initiatives **. Companies across all industries are facing increasing and evolving scrutiny relating to their ESG policies, initiatives and disclosures from governments, regulators, investors, consumers, employees and other stakeholders. Increased and varied focus and activism related to ESG may hinder our ability to attract or retain employees and access to capital, as investors may reconsider their capital investment because of their assessment of our ESG practices** . In addition, some stakeholders may disagree with our goals and initiatives. Any failure, or perceived failure, by us to achieve our goals, further ~~or~~ **our** initiatives, adhere to our public statements, comply with federal, state or international **ESG** ~~environmental, social and governance~~ laws and regulations, or meet evolving and varied stakeholder expectations and standards could result in legal and regulatory proceedings against us and materially adversely affect our business, reputation, results of operations, financial condition and stock price. Federal, state, and local governments are beginning to respond to climate change issues. This increased focus on sustainability may result in new legislation or regulations and customer requirements that could negatively affect us. Environmental laws, for example, particularly with respect to climate change and the emission of greenhouse gases, are also becoming more stringent throughout the world. We may incur additional costs or be required to make changes to our operations ~~in order~~ to comply with any new regulations or customer requirements. Legislation or regulations that potentially impose restrictions, caps, taxes, or other controls on emissions of greenhouse gases such as carbon dioxide, could adversely affect our operations and financial results. ~~34~~ **Recently, the European Parliament' s Corporate Sustainability Reporting Directive (" CSRD ") came into effect, which requires impacted companies, including multi- national companies with an EU presence, to make extensive sustainability and climate- related disclosure. The state of California has also enacted a series of laws, which will require (i) disclosure of Scope 1, Scope 2 and Scope 3 GHG emissions by public and private companies with total annual revenues in excess of $ 1 billion and that do business in California, (ii) disclosure of climate- related financial risks by public and private companies with total annual revenues in excess of $ 500 million and that do business in California, and (iii) certain disclosures by businesses that market, sell and, in some cases, buy and use, voluntary carbon offsets, or that make certain environmental marketing claims in California. Additionally, climate- related disclosure rules have been proposed by the SEC, and, if adopted, would require the Company to make new climate- related disclosures, including certain climate- related metrics and greenhouse gas emissions data, information about climate- related targets and goals, transition plans, if any, and comply with attestation requirements. The EU, California and (if adopted) SEC rules will impose increased compliance costs and could lead to increased litigation risks related to disclosures made pursuant to the rules, either of which could materially and adversely affect our financial performance. 35**