UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 000-32259

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3267295**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

410 North Scottsdale Road, Suite 1300
Tempe, Arizona 85288
(Address of principal executive offices, including zip code)

(602) 742-2000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	**ALGN**	**The NASDAQ Stock Market LLC (NASDAQ Global Select Market)**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Securities Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $13.3 billion as of June 30, 2022 based on the closing sale price of the registrant's common stock on the NASDAQ Global Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 20, 2023, 76,610,319 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2023 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2022 are incorporated by reference into Part III of this Annual Report on Form 10-K.

ALIGN TECHNOLOGY, INC.

FORM 10-K
For the Year Ended December 31, 2022
TABLE OF CONTENTS

In addition to historical information, this annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, our expectations and intentions regarding our strategic objectives and the means to achieve them, our beliefs and expectations regarding macroeconomic conditions, including inflation, fluctuations in currency exchange rates, rising interest rates, market volatility, weakness in general economic conditions and recessions and the impact of efforts by central banks and federal, state and local governments to combat inflation and recession, our expectations and beliefs regarding customer and consumer purchasing behavior and changes in consumer spending habits, our expectations regarding the impact of the military conflict in Ukraine generally and specifically regarding our operations and assets in Russia, including the impact on our workforce located in Russia, our expectations regarding the near and long-term implications of the COVID-19 pandemic on the global and regional economies, our marketing and efforts to build our brand awareness, our estimates regarding the size and opportunities of the markets we are targeting along with our expectations for growth in those markets, our beliefs regarding the impact of technological innovation in general, and in our solutions and products in particular, on target markets and patient care, our beliefs regarding digital dentistry and its potential to impact our business, our intentions regarding expanding our business, including its impact on our operational flexibility and responsiveness to customer demand, our beliefs regarding the potential for clinical solutions and their utilization to increase sales of our Invisalign system as well as the complementary products and solutions themselves, our beliefs regarding doctor training and its impact on Invisalign system utilization, our beliefs regarding the importance of our manufacturing operations on our success, our beliefs regarding the need for and benefits of our technological development on Invisalign treatment, the areas of development in which we focus our efforts, and the advantages of our intellectual property portfolio, our beliefs regarding our business strategy and growth drivers, our expectations regarding product mix and product adoption, our expectations regarding the utilization rates for our products, including the impact of marketing on those rates and causes for periodic fluctuations of the rates, our expectations regarding the existence and impact of seasonality, our expectations regarding the sales growth of our intraoral scanner sales in international markets, our expectations regarding the productivity impact additional sales representatives will have on our sales and the impact of specialization of those representatives in sales channels, our expectations regarding the continued expansion of our international markets and their growth, our expectations regarding competition and our ability to compete in our target markets, our expectations regarding staying in compliance with laws and regulations currently applicable to, or which may become applicable to, our business both in the United States and internationally, our beliefs regarding our culture and commitment and its impact on our financial and operational performance and its importance to our future success, our expectations for future investments in and benefits from consumer demand sales and marketing activities, our preparedness and our customers' preparedness to react to changing circumstances and demand, our expectations for our expenses and capital obligations and expenditures in particular, our intentions to control spending and for investments, our intentions regarding the investment of our international earnings from operations, our belief regarding the sufficiency of our cash and investment balances and borrowing capacity, our judgments regarding the estimates used in our revenue recognition and assessment of goodwill and intangible assets, our expectations regarding our tax positions and the judgements we make related to our tax obligations, our predicted level of operating expenses and gross margins and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies. These statements may contain words such as "expects," "anticipates," "intends," "plans," "believes," "estimates," or other words indicating future results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in particular, the risks discussed below in Part I, Item 1A "Risk Factors." We undertake no obligation to revise or update these forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

PART I

Business.

Our Company

Align Technology, Inc. ("We", "Our", "Align") is a global medical device company primarily engaged in the design, manufacture and marketing of Invisalign® clear aligners for the treatment of malocclusions, or the misalignment of teeth, by orthodontists and general dental practitioners ("GPs"), Vivera® retainers for retention, iTero® intraoral scanners and services for dentistry, and exocad® computer-aided design and computer-aided manufacturing ("CAD/CAM") software for dental laboratories and dental practitioners. Our vision and strategy is to revolutionize orthodontic and restorative dentistry through digital treatment planning and implementation using our Align Digital Platform™, an integrated suite of proprietary technologies and services designed to deliver a seamless, end-to-end solution for patients and consumers, orthodontists and GPs and lab partners. We strive to achieve our vision and strategy through key objectives made possible with the proprietary technologies and services of the Align Digital Platform to establish: clear aligners as the principal solution for the treatment of malocclusions with the Invisalign System as the treatment solution of choice by orthodontists, GPs and patients globally, our

intraoral scanners as the preferred scanning technology for digital dental scans, and our exocad CAD/CAM software as the dental restorative solution of choice for dental labs.

Align's corporate headquarters are located at 410 North Scottsdale Road, Suite 1300, Tempe, Arizona 85288. Our telephone number is 602-742-2000. Our internet address is www.aligntech.com. Our Americas regional headquarters is located in Raleigh, North Carolina, U.S.A.; our European, Middle East and Africa ("EMEA") regional headquarters is located in Rotkreuz, Switzerland; and our Asia Pacific ("APAC") regional headquarters is located in Singapore.

We have two operating segments: (1) Clear Aligner and (2) Imaging Systems and CAD/CAM Services ("Systems and Services"). For the year ended December 31, 2022, Clear Aligner net revenues represented approximately 82% of worldwide net revenues, while Systems and Services net revenues represented the remaining 18%. We sell the majority of our products directly through a dedicated and specialized sales force to our customers: orthodontists, GPs, including prosthodontists, periodontists, and oral surgeons, and dental laboratories. We also sell through sales agents and distributors in certain countries. In addition, we sell directly to Dental Support Organizations ("DSOs") who contract with dental practices to provide critical business management and support including non-clinical operations, and we sell products used by dental laboratories who manufacture or customize a variety of products used by licensed dentists to provide oral health care. We also market and sell doctor and consumer accessory products that are complementary to our doctor-prescribed principal products under the Invisalign® and other brands, including retainers, dental supplies, aligner cases (clamshells), teeth whitening products and cleaning solutions (collectively "Invisalign Accessory Products"). Depending on the product, our Invisalign Accessory Products are sold through a variety of channels, including online through large e-commerce websites, our doctor portal and in-store through large retailers and pharmacy stores.

Our clear aligners are sold under the Invisalign® brand name. Our Invisalign System is intended mainly for the treatment of malocclusions and is designed to help dental professionals achieve the clinical outcomes that they expect and the results patients desire. To date, over 14 million people worldwide have been treated with our Invisalign System. In order to provide Invisalign treatment to their patients, orthodontists and GPs must initially complete an Invisalign training course. Our iTero intraoral scanner is used by dental professionals and/or labs and service providers for restorative and orthodontic digital procedures as well as Invisalign case submissions. Our exocad CAD/CAM software products provide restorative dentistry, implantology, guided surgery, and smile design to dental labs and dental practices through fully integrated workflows, paving the way for new, cross-disciplinary dentistry in labs and at chairside.

Our Products, Services and Technologies

Align Digital Platform

We strive to be at the forefront of innovation in digital orthodontics and dentistry, helping doctors transform their practices using digital tools and technology to deliver great treatment experiences and outcomes to people worldwide. The Align Digital Platform is the foundation of our goal to revolutionize the practice of dentistry, delivering interconnected, interdisciplinary workflows and treatment solutions that move all aspects of treatment forward, from first consultations to final smiles with our doctor-centered treatment model. It is an end-to-end digital platform that combines software, systems and services to seamlessly integrate and connect those critical to successful treatment outcomes – doctors, labs, patients, and consumers. At the center of the Align Digital Platform are Invisalign clear aligners, iTero intraoral scanners, and exocad CAD/CAM software.

The Align Digital Platform utilizes the Align Digital Workflow to enable an end-to-end treatment experience with the following key components:

- **Connect:** The initial stage of the platform drives consumer demand and connects potential patients to our websites and Invisalign providers. Some of our tools that support this stage are Invisalign.com, the Invisalign SmileView tool, My Invisalign app, Doctor Locator, Invisalign Practice App, Invisalign Doctor Estimate and Invisalign Virtual Appointment.
- **Scan:** During this stage, patient data is captured through intraoral scanning. Tools support a patient's diagnosis of oral conditions and health and support the identification of an appropriate treatment pathway. Visualization of their potential smile helps patients understand the benefits of treatment and increase patient conversion. The tools that support this stage, include, iTero scanners and imaging systems, Invisalign Outcome Simulator Pro, Invisalign Photo Uploader, iTero NIRI technology (Near Infra-Red Imaging), iTero TimeLapse technology, iTero Element 5D auto upload feature and iTero Scan Report.
- **Plan:** Doctors digitally visualize and plan orthodontic and restorative treatments. Orthodontists and GPs can use our products to design, build and share their vision for treatment planning and agree on a customized plan with their patients to reach the desired outcomes. Orthodontists and GPs can use our products to design, build and share their vision for treatment planning and agree on a customized plan with their patients to reach the desired outcomes. Some of our tools that support this stage are ClinCheck Pro® 6.0, ClinCheck In-Face Visualization, ClinCheck Live Update, Invisalign Practice App, Invisalign Personalized Plan and CBCT integration for ClinCheck software.
- **Treat:** During this stage, doctors treat their patients with our Invisalign® clear aligners.
- **Monitor:** Doctors are able to remotely track their patient's treatment between visits, and orthodontists and GPs can more easily communicate treatment progress and tracking to their patients. Some of our tools that support this stage include Invisalign Virtual Care app, My Invisalign app, Invisalign Doctor Site, Invisalign Practice App, Invisalign Progress Assessment and iTero scanners.
- **Retain:** Patients retain the final position of their treatment results through our Vivera® retainers.

As we further evolve the treatment planning experience for doctors leveraging 25 years in technological research and development innovations, we expect to introduce new technologies, features and functionality that improve personalization of treatment planning, predictability, clinical preferences, and 2D/3D imaging, including digital tools for faster and more accurate final tooth positions. In 2022, we launched significant new products and technologies that further enhance the Align Digital Platform, including the ClinCheck® Live Update software, Invisalign® Practice App, Invisalign® Personalized Plan, Invisalign Smile Architect™, Invisalign® Outcome Simulator Pro with in-face visualization, Cone Beam Computed Tomography integration with ClinCheck software, Invisalign® Virtual Care AI software, and the iTero-exocad Connector.

Clear Aligner Segment

Malocclusion and Traditional Orthodontic Treatment

Malocclusion is one of the most prevalent clinical dental conditions in the world, affecting approximately 60% to 75% of the global population. We estimate that there are approximately 500 million people globally with malocclusion who could benefit from straightening their teeth. However, most people afflicted by malocclusion do not seek orthodontic treatment due to a number of reasons, including negative perceptions of metal braces, affordability of treatment, and accessibility to doctors in

certain markets and geographies. Annually, only approximately 21 million people globally elect treatment by orthodontists. Today, most orthodontic patients continue to have their malocclusions treated with the use of traditional corrective methods such as metal arch wires and brackets, referred to as braces, augmented with elastics, metal expanders, headgear or functional appliances, and other ancillary devices as needed. Upon completion of a patient's treatment, their dental professional may recommend the patient use a retainer appliance to preserve the benefits of their treatments. Of the 21 million cases started, we estimate that approximately 90% (19 million) can be treated using our Invisalign System, yet our share of the 21 million case starts through orthodontists is approximately 10% globally. This represents a significant growth opportunity for us to increase our share of the existing market of orthodontic case starts, especially among teens, and expand the market for digital orthodontics, especially among adults. By training more doctors, including GPs as well as orthodontists, educating more consumers about the benefits of straighter teeth using the Invisalign System and connecting consumers with an Invisalign-trained doctor of their choice, we are helping drive adoption of digital orthodontics and restorative dentistry globally.

The Invisalign System

The Invisalign System is a proprietary method for treating malocclusion based on a proprietary computer-simulated virtual treatment plan and a series of doctor-prescribed, custom manufactured, clear polymer removable aligners. We received 510(k) clearance from the United States ("U.S.") Food and Drug Administration ("FDA") to market the Invisalign System in 1998. The Invisalign System offers a range of treatment options, specialized services, and access to proprietary software for treatment visualization and is comprised of the following phases:

Diagnosis and transmission of treatment data. An Invisalign trained dental professional prepares an online prescription form on our Invisalign Doctor Site and securely submits the patient's records, which include a digital intraoral scan or a polyvinyl-siloxane ("PVS") impression of the relevant dental arches, photographs of the patient and, at the dental professional's election, x-rays of the patient's dentition. Intraoral digital scans may be submitted through Align's iTero scanner or certain third-party scanners capable of accurately interfacing with our systems and processes. Globally, more than 89% of Invisalign System prescription orders are now submitted via digital scan, increasing the accuracy of treatments, reducing the time from prescription submission to patient receipt, and decreasing the carbon footprint resulting from the shipment of the materials used to form PVS impressions to the doctors and shipping those PVS impressions back to us. Additionally, it is during this stage that exocad's CAD/CAM software platform can be used to identify, assess and assist doctors and dental labs to collaborate on any needed ortho-restorative treatment options through comprehensive interdisciplinary workflows.

Computer-simulated treatment plan. Using the digital scans or PVS impressions, certain doctor preferences and digital data provided, we generate a proposed custom, three-dimensional treatment plan, called a ClinCheck® treatment plan, using proprietary software developed through significant, ongoing research and development investments spanning more than two decades. A patient's ClinCheck treatment plan simulates desired tooth movement in stages and details the timing and placement of any features or attachments to be used during treatment. Attachments are tooth-colored "buttons" that are sometimes used to increase the biomechanical force on a specific tooth or teeth in order to affect the desired movement(s).

Review and approval of the treatment plan by an Invisalign trained doctor. The patient's ClinCheck treatment plan is then made available to the prescribing dental professional via Align's Invisalign Doctor Site, enabling the dental professional to evaluate projected tooth movement from initial to final position and compare multiple treatment plan options. By reviewing, modifying as needed and approving the treatment plan, the dental professional retains control of the patient's treatment.

Manufacture of custom aligners. Following the dental professional's approval of a ClinCheck treatment plan, we use the data underlying the simulation as input for the next stage of the Align Digital Workflow in which we use stereolithography technology (a form of 3D printing technology) to construct a series of molds depicting the future position of the patient's teeth. Each mold is a replica of the patient's teeth at each stage of the simulated course of treatment. From these molds, aligners are fabricated by pressure-forming polymeric sheets over each mold. Aligners are thin, clear polymer, removable dental appliances that are custom manufactured in a series designed to correspond to each stage of the patient's ClinCheck treatment plan.

Shipment to the dental professional and patient aligner wear. Once manufactured, all the aligners for a patient's doctor-approved treatment plan are typically shipped directly to the dental professional, who then dispenses them to the patient at regular check-up intervals. Aligners are generally worn for a short period of time corresponding to the stages of the patient's approved ClinCheck treatment plan and their doctor's discretion. The patient replaces the aligners with the next pair in the series when prescribed, advancing tooth movement through each stage. At various points in each patient's treatment, their doctor may place attachments or use other auxiliaries to achieve desired tooth movements, per the doctor's original prescription and the approved ClinCheck treatment plan. Additionally, for patients treated using many of our Invisalign System products, doctors have the option to adjust treatment plans to achieve desired results by ordering additional clear aligners in accordance with pre-defined terms.

Clear Aligner Products

We offer our Invisalign System in a variety of treatment packages designed to correspond with the case-by-case treatment needs of our doctors and their patients. The table below provides a general description of the categories of Invisalign System products offered in various regions as they typically correspond to the severity of malocclusion and length of anticipated treatment.

Malocclusion	**Very Mild**	←	**Moderate**	→	**Severe**
Product	Invisalign® Express Package	Invisalign® Lite Package	Invisalign Go™ Limited Movement (GP)	Invisalign® Moderate Packages (& Invisalign Go™ Plus)	Invisalign® Comprehensive Packages
Treatment Stages*	7	14	20	20-26	As many as required
Clinical Scope	Relapse and minor movement, anterior esthetic alignment	Class I, mild crowding/spacing, non-extraction, pre-restorative	Class I, no anterior / posterior correction, mild to moderate crowding, spacing, non-extraction, pre-restorative Tooth movement from 2nd premolar to 2nd premolar (5x5)	Class I, mild Class II, mild to moderate crowding/spacing, mild anterior / posterior and vertical discrepancies, pre-restorative, (Go Plus tooth movement from 1st molar to 1st molar (6X6))	Class I, II, III, moderate to severe crowding/spacing, anterior / posterior and vertical discrepancies, extractions, complex pre-restorative

* The number of stages can vary by product and region.

Most of our Invisalign System products described above provide dental professionals with the option to order additional aligners if the patient's treatment deviates from the original treatment plan. The number and timing of additional aligner orders are subject to certain requirements noted in our terms and conditions.

Comprehensive Products - Invisalign Treatment Options:

Invisalign Comprehensive Packages. The Invisalign Comprehensive Package is used to treat adults and teens over a wide spectrum of mild to severe malocclusion and contains a broad variety of features to address the desired treatment goals. It also addresses the frequently complex orthodontic needs of teenage or younger patients with advanced features such as mandibular advancement, compliance indicators and compensation for tooth eruption. These packages include Invisalign Comprehensive, Invisalign First Phase 1 and Invisalign First Comprehensive Phase 2.

Invisalign First Phase 1 and Invisalign First Comprehensive Phase 2 Packages. Invisalign First Phase 1 Package is designed specifically for younger patients generally between the ages of six and ten years, who frequently have a mixture of primary/baby and permanent teeth. Invisalign First Phase 1 treatment provides early interceptive orthodontic treatment, traditionally done through arch expansion, or partial metal braces, before all permanent teeth have erupted. Invisalign First Phase 1 clear aligners are designed specifically to address a wide range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition and predictable dental arch expansion. Our Invisalign First Comprehensive Phase 2 Package complements Invisalign First Phase 1 and is generally consistent with our Invisalign Comprehensive Package. After a patient completes Invisalign First Phase 1, doctors have the option to purchase a Comprehensive Phase 2 Package for that same patient.

Non-Comprehensive Products - Invisalign Treatment Options:

Invisalign Non-comprehensive Packages. We offer a variety of lower priced treatment packages for less complex orthodontic cases, non-comprehensive relapse cases, or teeth straightening prior to restorative or cosmetic treatments, such as veneers. These treatment packages include Invisalign Express, Invisalign Lite, Invisalign Go, Invisalign Go Express and Invisalign Moderate. These packages may be offered in select countries and/or may differ from region to region.

Invisalign Go Packages. In various markets we also offer Invisalign Go and Invisalign Go Plus, streamlined Non-Comprehensive packages designed for GPs to more easily identify and treat patients with mild malocclusion. The Invisalign Go and Invisalign Go Plus packages include case assessment support, simplified ClinCheck treatment plans and a progress assessment feature for case monitoring.

Feature Enhancement / New Products

Invisalign Mandibular Advancement. Invisalign System with mandibular advancement is designed for tweens and teens. It is targeted for patients with permanent teeth or stable baby teeth who have bite issues in which the lower jaw is further back and can benefit from being brought forward for a better bite relationship. The Invisalign System with mandibular advancement addresses Class II bite correction with simultaneous alignment of the teeth. In 2022, we enhanced the original design with new enhanced precision wings that provide increased durability and comfort, as well as greater overlap to help the aligners remain properly engaged to keep the patient's lower jaw forward during treatment.

Non-Case Products:

Clear Aligner non-case products include retention products, Invisalign training, adjusting tools used by dental professionals during the course of treatment, ancillary Invisalign Accessory Products and other oral health products available in certain e-commerce and retail channels in the U.S.

Retention. We offer up to four sets of custom clear aligners called Vivera retainers made with proprietary material strong enough to maintain tooth position and correct minor relapse, if necessary, as well as Invisalign retainers. Retainers are generally available for doctors to offer to any of their patients, whether they use the Invisalign System or other products, including wires and brackets. In select markets, we also offer single set retainers. Additionally, we offer a professional whitening system using Ultradent's Opalescence PF whitening system with Vivera retainers.

We also offer in the U.S., a Doctor Subscription Program which is a monthly subscription program based on the doctor's monthly need for retention or limited treatment. The program allows doctors the flexibility to order both "touch-up" or retention aligners within their subscribed tier and is designed for a segment of experienced Invisalign trained doctors who are currently not regularly using our retainers or low-stage aligners.

Smart Technology: SmartTrack, SmartForce and SmartStage

Smart technology is applied in the development of Invisalign treatments and leads to a more precise control of individual and multiple tooth movements. We use a force driven system in our Invisalign treatments such that the next aligner is shaped so that when inserted, the aligner stretches and applies the desired forces to the surface of the tooth, resulting in the desired tooth movement. Smart technology allows us to find the right thickness, the right elasticity, and the right force application over a period of time. Smart technology includes the use of SmartTrack, SmartForce and SmartStage Technology.

SmartTrack. SmartTrack clear aligner material is a patented, custom-engineered Invisalign clear aligner material that delivers gentle, more constant force considered ideal for orthodontic tooth movements. Conventional aligner materials relax and lose a substantial percentage of the force applied in the initial days of wear. SmartTrack material maintains more constant force over time. The flexible SmartTrack material also more precisely conforms to tooth morphology, attachments and interproximal spaces to improve control of tooth movement throughout treatment.

SmartForce. SmartForce attachments are small tooth-colored shapes that are attached to teeth before or during Invisalign treatment. Invisalign clear aligners fit smoothly and tightly around the attachments and give the aligners something to gently push on. SmartForce attachments make complex tooth movements possible without braces by helping clear aligners apply the right amount of force in the right direction.

SmartStage Technology. SmartStage is an advanced algorithm that determines the optimal path of tooth movement and the shape of the aligner at every stage of an Invisalign treatment. The programming determines tooth movement in a certain sequence, at the right time to achieve optimal outcomes with greater predictability and fewer undesirable interferences.

Systems and Services Segment

Intraoral scanning is a rapidly evolving technology that is having a substantial impact on the practice of dentistry. By enabling the dental practitioner to create a 3D image of a patient's teeth (digital scan) using a handheld intraoral scanner, digital scanning is faster, more efficient, precise and comfortable for patients. Beginning patient care with the early usage of our iTero intraoral scanners and combining the results with digital workflows designed to assist doctors and patients visualize and evaluate various treatment options with detailed imagery and CAD/CAM solutions is helping patients decide to undergo treatment and improve treatment outcomes and satisfaction. The accuracy of digitally scanned models substantially reduces the rate of restoration "remakes," meaning patients are recalled less often and the appointment time for the restoration is shorter because of fewer adjustments, increasing overall patient satisfaction. Digital models also reduce the carbon footprint associated with the shipping of the materials used to create PVS impressions, the shipping of those impressions and their disposal.

Moreover, the digital model file can be used for various procedures and services including fabrication of physical dental models for use by labs to create restorative units such as veneers, inlays, onlays, crowns, bridges and implant abutments; digital records storage; aid to caries detection; orthodontic diagnosis; orthodontic retainers and appliances; and Invisalign digital impression submission.

iTero Scanner. The iTero Element™ portfolio of intraoral scanners includes the iTero Element™ 2, the iTero Element™ Flex, iTero Element™ 5D Imaging System and iTero Element™ Plus Series which are each available in select regions and countries. These products build on the existing high precision, full-color imaging and fast scan times of the iTero Element portfolio and are available with software options for orthodontic and restorative procedures. The iTero scanner is interoperable with our Invisalign System such that a full arch or full mouth digital scan can be submitted as part of the Invisalign System prescription order submission process.

Our iTero Element 5D Imaging System is the first integrated dental imaging system that simultaneously records 3D, intraoral color camera images, near infrared imaging ("NIRI") technology and enables comparison over time using the iTero™ TimeLapse technology. NIRI technology, included in our iTero Element 5D and 5D Plus Imaging Systems, aids in detection and monitoring of interproximal caries lesions above the gingiva without using harmful radiation. The iTero Element 5D Imaging System is available in the U.S., Canada, China, and the majority of EMEA and select APAC and LATAM countries and is pending regulatory approval in others. We received 510(k) clearance in the U.S. for the caries detection feature of the iTero Element 5D in 2020. The iTero Element Plus Series of intraoral scanners and imaging systems offers restorative and orthodontic digital workflows that include enhanced visualization for optimized patient experience, including a fully integrated 3D intraoral camera in certain models, seamless scanning with reduced processing time, artificial intelligence-based features, and, in certain models, NIRI technology.

Our iTero Element scanners are offered in a number of software configurations such as Ortho Comprehensive, Restorative Comprehensive and Restorative Foundation. These software packages are included in the price of the scanner and have a service period of 1 to 5 years. They enable various orthodontic and restorative workflows as well as provide other applications, including Invisalign Outcome Simulator, Invisalign Case Assessment tool, Invisalign Progress Assessment tool, and iTero TimeLapse technology. Our iTero software is designed for orthodontists for digital records storage, orthodontic diagnosis, and for the fabrication of printed models and retainers. Our Restorative software is designed for GPs, prosthodontists, periodontists and oral surgeons and includes restorative workflows providing the ability to send digital impressions to the lab of their choice and communicate seamlessly with external treatment planning, custom implant abutment, chairside milling and laboratory CAD/CAM systems such as through our exocad Connector.

Invisalign® Outcome Simulator. The Invisalign Outcome Simulator is an exclusive chair-side and cloud-based application for the iTero scanner that allows doctors to help patients visualize how their teeth may look at the end of Invisalign treatment. This is achieved through a dual view layout that shows a prospective patient an image of their own current dentition next to a simulated final position after Invisalign treatment.

Invisalign® Progress Assessment Tool. The Invisalign Progress Assessment tool provides the ability to compare a patient's new scan with a specific stage of their ClinCheck® treatment plan, allowing doctors to visually assess and communicate Invisalign treatment progress with an easy-to-read, color-coded, tooth movement report.

iTero® TimeLapse Technology. Our iTero® TimeLapse technology allows doctors or practitioners to compare a patient's historic 3D scans to a present-day scan, enabling clinicians to identify and measure orthodontic movement, tooth wear, and gingival recession. This highlights areas of diagnostic interest to dental professionals and helps foster a proactive conversation with the patient regarding potential restorative or orthodontic solutions.

*CAD/CAM Service*s. Our exocad CAD/CAM software platform addresses restorative needs in an end-to-end digital platform workflow to facilitate ortho-restorative and comprehensive dentistry. The platform provides doctors and dental labs with digital clinical solutions that aid GPs and dental labs in planning and delivering restorative dental treatments, adding restorative functionality to our comprehensive digital platform to deliver digital ortho-restorative workflows and interdisciplinary dentistry. Our exocad software is licensed and sold separately.

Other proprietary software mentioned in this Annual Report on Form 10-K, such as software embedded in our iTero scanners, ClinCheck and ClinCheck Pro software, the Invisalign Doctor Site, and feature enhancements included as part of the Invisalign System are not sold separately, nor do they contribute as individual items to revenues.

Business Strategy

Our technology and innovations are designed to meet the demands of today's patients with convenient, comfortable, and affordable treatment options, while improving overall oral health. We strive to help doctors and lab technicians move their businesses forward by connecting them with new patients, providing digital solutions that increase operational speed and efficiency and provide solutions that allow them to deliver exceptional treatment outcomes and experiences to millions of people around the world. We achieve this by focusing on and executing to our strategic growth drivers:

- *International Expansion.* We continue increasing our presence globally by making our products available in more countries to more customers. We continue expansion of our sales and marketing by reaching into new countries and regions, including new areas within Africa and Latin America. By the end of 2022, we were selling directly or through authorized distributors in more than 100 countries. As our business continues to grow in both number of new Invisalign trained doctors and customer utilization, we support that growth through targeted investments such as clinical support, product improvements, technological innovations, clinical education and advertising. In addition, we are scaling and expanding our operations and facilities to better support the growing numbers of global customers. In 2022, with the opening of our third clear aligner fabrication facility Wroclaw, Poland, we now have a manufacturing facility in each of our regions: Americas (Mexico), APAC (China), and EMEA (Poland). Each of these three facilities represents a "hub" and together these three hubs form the foundation of our "Regional Hub Model", which will continue to evolve as we consider additional locations to improve coverage and service for any potential future markets. We also perform digital treatment planning and interpretation for restorative cases worldwide, including in Costa Rica, China, Germany, Spain, Poland, and Japan, among others. By establishing and expanding our key operational activities in locations closer to our customers, we are creating an infrastructure that allows us to be responsive to local and regional needs, while providing global operational flexibility and scale needed for variations in global and regional demand. We expect to continue expanding our business in 2023 by investing in resources, infrastructure and initiatives that help drive Invisalign treatment growth, our intraoral scanners as the preferred scanning technology for digital dental scans, and our exocad CAD/CAM software as the solution of choice for dental labs in existing and new international markets.

- *GP Adoption*. We want to enable GPs, who have the potential to treat the general population, to more easily identify potential cases they can treat with the Invisalign System, monitor patient progress or, if needed, help refer cases to an orthodontist while providing high-quality restorative, orthodontic and dental hygiene care. We believe success with GPs can be achieved through doctor training and clinical education, by offering digital tools such as the iTero scanner and products like Invisalign Go™ treatment that address the distinctive needs of GP patients, all delivered by sales and marketing personnel specifically focused on the unique needs of this customer category. We encourage GPs to scan every patient with intraoral scanners that are without harmful radiation as a means to diagnose and treat patients over time and as an opportunity to drive future demand for their services and the Invisalign System. In October 2021, the findings of a clinical study we sponsored were published in the peer-reviewed Journal of Dentistry were validated and demonstrated that the NIRI technology of the iTero Element 5D imaging system was 66% more sensitive than bitewing x-ray radiography for detection of interproximal lesions, without the use of harmful radiation, which supports our belief in the benefits of using iTero scanners.

- *Patient Demand & Conversion.* Our goal is to make the Invisalign brand a highly recognized name brand worldwide by creating awareness for Invisalign treatment among consumers and motivating the potential 500 million patients who can benefit from treatment of malocclusion to seek treatment using the Invisalign System. We accomplish this through an integrated consumer marketing strategy that includes television, media, social networking and event marketing and strategic alliances with professional sports teams, as well as educating patients on treatment options and directing them to high volume Invisalign trained doctors. To further drive consumer awareness, in 2022, we continued to offer additional dental-related Invisalign Accessory Products under the Invisalign brand name available in certain e-commerce channels in the U.S.

- *Orthodontist Utilization.* We continue to innovate and increase product applicability and predictability to address a wide range of cases, from simple to complex, thereby enabling doctors to confidently diagnose and treat children and adults with the Invisalign System. This is especially important to treating teenage patients who make up the largest portion of the 21 million annual orthodontic case starts each year. We also continue to make improvements to our Invisalign treatment software, ClinCheck Pro software, designed to deliver an exceptional user experience and increase treatment control to help doctors achieve their treatment goals. In combination with the new Invisalign System innovations that are part of the Align digital platform, we are enhancing the digital treatment planning experience for orthodontics by providing doctors with greater flexibility, consistency of treatment preferences and real-time treatment plan access and modification capabilities.

Manufacturing and Suppliers

We have three manufacturing facilities for clear aligners, which are located in Juarez, Mexico, where we conduct our aligner fabrication, distribution, and certain services for the Americas market, Ziyang, China, where we fabricate aligners for China and other APAC markets and Wroclaw Poland, where we fabricate aligners for EMEA markets. We have designed this Regional Hub Model to primarily cater to our respective market areas, enable us to better serve our global customer base by being closer to our doctor customers and drive efficiencies in the business. We produce our handheld intraoral scanner wand, perform final scanner assembly and repair our scanners at our facilities in Ziyang, China and Petah Tikva, Israel and service and repair certain scanners in Juarez, Mexico.

We also perform digital treatment planning and interpretation for restorative cases based on digital scans generated by our iTero intraoral scanners. Our digital treatment planning facilities are located worldwide, including in Costa Rica, China, Germany, Spain, Poland and Japan, among other international locations.

Our quality system is required to be in compliance with the Quality System regulations enforced by the FDA, and similar regulations enforced by other worldwide regulatory authorities. We are certified to ISO 13485:2016, an internationally recognized standard for medical device quality. We are routinely audited by third party certification bodies as well as global health authorities for our compliance to this quality standard as well as international regulations. We have a formal, documented quality system by which quality objectives are defined, understood and achieved. Systems, processes and procedures are implemented to ensure high levels of product and service quality. We monitor the effectiveness of the quality system based on internal data and direct customer feedback and strive to continually improve our systems and processes, taking corrective action, as needed.

Since the mass-customized treatment planning and manufacturing processes of our products requires substantial and varied technical expertise, we believe that our manufacturing capacity and capabilities are important to our success. In order to produce our highly-customized, highly-precise, medical quality products in volume, we have developed a number of proprietary processes and technologies. These technologies include complex software algorithms and solutions, including artificial intelligence and machine-learning based CAD/CAM software, Vision systems, CT scanning, stereolithography and automated custom aligner fabrication equipment. To increase the efficiency and yield of our manufacturing processes, we continue to focus our efforts on software development, equipment development and the improvement of rate-limiting processes or bottlenecks. We continuously upgrade our proprietary, three-dimensional treatment planning software to enhance computer analysis of treatment data and to reduce time spent on manual and judgmental tasks for each case, thereby increasing the efficiency of our technicians. In addition, to improve efficiency and increase the scale of our operations, we continue to invest in the development of automated systems for the fabrication and packaging of aligners.

In addition, predictable and consistent production is essential to our commitment to timely deliver products to our customers efficiently and profitably. Our production can be disrupted by such things as supply chain issues, production manufacturing software system issues and production equipment downtime. Accordingly, as we have grown our operations, we have included flexibility and resiliency in our overall manufacturing design to mitigate the risks of production downtime. Our manufacturing facilities include backup generators and systems and each facility has an emergency response plan that is part of ongoing employee training and testing through recurring cross functional scenario-based simulation exercises. Likewise, the Regional Hub Model provides us with greater flexibility and capacity to redirect production to one or more of our production facilities as needed.

As part of our manufacturing resiliency design efforts, we have also considered climate change, climate-related risks - higher average global temperatures, rising sea levels and more frequent and severe wildfires, hurricanes, floods, winter storms, heat waves and other events and natural disasters (collectively, “climate-related risks”). We view climate-related risks to be one of many operational challenges we face, and factor them into our business continuity planning and strategic risk mitigation efforts.

For instance, our manufacturing plants and operations may be impacted by extreme temperatures and weather, subjecting us to potential brownouts and blackouts, increased energy costs and capital investments needed to maintain ideal operating temperatures. Our manufacturing facility in Juarez, Mexico is located in an area classified as high-water stress and our operations could be impacted by water shortages, rationing and droughts. Our California, Costa Rica, Mexico and North Carolina operations are located in areas that have historically been impacted by extreme weather events such as hurricanes, tornados, wildfires or flooding.

In part to help mitigate risks to our manufacturing operations, we have strategically located our clear aligner production facilities in three facilities on different continents. This allows us to both respond more quickly to customer demand while also

offering redundancy in the event natural disasters or climate-related events affect operations at one or more facilities. Moreover, each of our three key clear aligner manufacturing facilities are located at elevations less likely to be impacted by rising sea levels and at least two hundred miles inland.

Moreover, we are highly dependent on manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials for our aligners, as well as the optics, electronic and other mechanical components of our intraoral scanners. We maintain single supplier relationships for many of these machines and materials technologies. In particular, our CT scanning and stereolithography equipment used in our aligner manufacturing and many of the critical components for the optics of our intraoral scanners are provided by single or sole source suppliers. We also currently purchase our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, from a single source. A discussion of the risks of our supply and manufacturing operations, including foreign operations, may be found in Item 1A of this Annual Report on Form 10-K under the heading "Risk Factors."

Sales and Marketing

Our sales and marketing efforts are focused on increasing adoption and utilization of the Invisalign System and Vivera retainers by orthodontists and GPs worldwide and integrating the iTero scanner and services and exocad CAD/CAM products into dental labs and practices. The iTero scanner is an important component to the customer experience and is central to a digital approach as well as overall customer utilization of Invisalign clear aligners. In each region, we have direct sales, marketing and support organizations, which include quota carrying sales representatives, sales management and sales administration. We also have distribution partners in certain markets. Our sales and marketing personnel are organized primarily to support orthodontists and GPs separately, allowing highly trained and specialized personnel to serve each customer channel, thereby increasing our focus and effectiveness on both. We continue to expand in existing markets through targeted investments in sales resources, professional marketing and education programs. Additionally, our consumer marketing programs are designed to create awareness and educate consumers on the benefits of Invisalign treatment and Vivera retainers, including where they can find a trained doctor to provide treatment.

We provide training, marketing and clinical support to orthodontists and GPs. As of December 31, 2022, we had approximately 124,500 active Invisalign trained doctors. We define doctors as active if they have submitted at least one Invisalign case in the prior 12-month period.

Research and Development

We are committed to investing in world-class digital technology development, which we believe is critical to achieving our goal of establishing the Invisalign System as the standard method for treating malocclusion, our intraoral scanners as the preferred scanning technology for digital dental scans, and our exocad CAD/CAM software as the solution of choice for dental labs.

Our research and development activities are directed toward developing digital technology innovations that we believe will deliver our next generation of products and solutions to enable the Align Digital Platform. These activities range from accelerating product and clinical innovation to developing manufacturing process improvements to researching future technologies, products and software.

In an effort to demonstrate the broad treatment capabilities of the Invisalign System, various clinical case studies and articles have been published that highlight the clinical applicability of Invisalign treatment to malocclusion cases, including those of severe complexity. Similarly, various studies have also been published demonstrating the capabilities of our scanners, including advanced features such as our NIRI technology. We undertake pre-commercialization trials and testing of our technological improvements to our products and manufacturing process. We furthermore fund research in the field of orthodontics and dentistry through initiatives such as our Annual Research Award Program, which was in its 13th year in 2022, our donations to the American Association of Orthodontists Foundation and our partnership with MedTech Innovator Asia Pacific, a nonprofit startup accelerator for the medical technology industry that connects healthcare industry leaders with innovative medical technology startups for mentorship and support.

Intellectual Property

We believe our intellectual property portfolio represents a substantial business advantage. As of December 31, 2022, we had 739 active U.S. patents, 831 active foreign patents, and 813 pending global patent applications. Our active U.S. patents expire between 2023 and 2041. When patents expire, we lose the protection and competitive advantages they provided, which could negatively impact our operating results; however, as we continue to pursue new innovations, we seek intellectual property protection for new inventions and know-how through U.S. and foreign patent applications and non-disclosure agreements. We

also seek to protect our software, documentation and other written materials under trade secret and copyright laws. We furthermore have a broad and diverse trademark portfolio that we use to highlight and protect our universally recognized brands. Information regarding risks associated with our proprietary technology and our intellectual property rights may be found in *Item 1A* of this Annual Report on Form 10-K under the heading *"Risk Factors."*

Seasonal Fluctuations

General economic conditions impact our business and financial results, and we have historically experienced seasonal trends within our two operating segments, customer channels and the geographic locations that we serve. Sales of the Invisalign system are often weaker in Europe, especially southern European countries during the summer months due to our customers and their patients being on holiday and seasonally higher in China during the third quarter. Similarly, other international holidays like Lunar New Year can impact our sales in APAC. In North America, summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients as many parents want to get their teenagers started in treatment before the start of the school year; however, many GPs are on vacation during this time and therefore tend to start fewer cases. For our Systems and Services segment, capital equipment sales are often stronger in the fourth calendar quarter. Consequently, these seasonal trends have caused and may continue to cause fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates. However, our typical seasonal patterns have been impacted by macroeconomic uncertainty including significant changes in foreign exchange rates, the effects of COVID-19 , the military conflict between Russia and Ukraine and other macroeconomic challenges, and it remains unclear when or if they will return to historical norms.

Competition

Our clear aligner products compete directly against traditional orthodontic treatments that use metal brackets and wires and increasingly against clear aligner products manufactured and distributed by various companies, both within and outside the U.S. Although the number of competitors varies by segment, product, geography and customer, they include new and well-established regional competitors in certain foreign markets, as well as larger companies, divisions of larger companies or well-capitalized new entrants with substantial sales, marketing, research and financial capabilities. Competition in the clear aligner market continues to increase. In addition, corresponding foreign patents began expiring in 2018 which has increased competition outside the U.S. These competitors include existing larger companies in certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us, direct-to-consumer ("DTC") companies that provide clear aligners requiring little or no in-office care from trained and licensed doctors themselves who can manufacture retainers and custom aligners for treatment of very simple malocclusion in their offices using modern 3D printing technology. Unlike our DTC competitors, we are committed to doctors being at the core of our business strategy, and Invisalign treatment requires a doctor's prescription and an in-person physical examination of the patient's dentition before treatment can begin.

Additionally, we face competition in the emerging and rapidly evolving markets for intraoral scanners and software solutions, including CAD/CAM. The global intraoral scanner market is very dynamic with participants spanning from traditional dental conglomerates to companies dedicated primarily to scanner development and sales with new entrants from South Korea and China playing larger roles. The iTero intraoral scanner competes with PVS impressions that doctors use for clear aligner therapy or other dental procedures, as well as other intraoral scanners. It also competes with traditional bite wing 2D dental x-rays for detecting interproximal caries. Information regarding risks associated with increased competition may be found in *Item 1A* of this Annual Report on Form 10-K under the heading "*Risk Factors*."

We believe we are well positioned to compete in the markets we target. We have a dedicated, highly skilled sales force of over 4,000 employees who are focused on key demographics in our target markets that allow us to uniquely address customer needs and thereby enhance the customer experience. Our significant historical and ongoing investments in research and development and design around the movement of teeth, SmartTrack aligner materials and design, intraoral scanning, 3D manufacturing, global scale of manufacturing and treatment planning, strong brand name recognition, and an in depth understanding of the drivers and motivations within the orthodontic and GP dental markets are among a few of our key competitive factors that compare favorably with our competitors' products and services.

Government Regulation

Many countries throughout the world have established regulatory frameworks for commercialization of medical devices. As a designer, manufacturer, and marketer of medical devices, we are obligated to comply with the respective frameworks of these countries to obtain and maintain access to these global markets. The frameworks often define requirements for marketing authorizations which vary by country. Failure to obtain appropriate marketing authorization and to meet all local requirements, including specific quality and safety standards in any country in which we currently market our products, could cause commercial disruption and/or subject us to sanctions and fines. Delays in receipt of, or a failure to receive, such marketing

authorizations, or the loss of any previously received authorizations, could have a material adverse effect on our business, financial condition and results of operations.

With regards to premarket authorization in the U.S., many of our products are classified as medical devices under the U.S. Food, Drug, and Cosmetic Act ("FD&C Act"). The FD&C Act requires these products, when sold in the U.S., to be safe and effective for their intended use and to comply with medical device regulations defined by the FDA. The regulatory framework depends on a set of written processes for ensuring consistent quality called a Quality Management System ("QMS") coupled with a product marketing authorization which depends on the risk classification of the product. This regulatory framework is comparable to the framework established in the European Union ("EU"). Within the EU, our products are subject to the requirements defined by the Medical Device Regulation EU 2017/745 which replaced the Medical Device Directive 93/42/EEC with a final transition date of May 26, 2021. Similar market access regulations exist in Brazil, China, Japan and other countries. Our QMS is routinely audited by certification bodies as well as country regulators for compliance with applicable regulations. We believe we are in compliance with all state, federal, and international regulatory requirements applicable to our products.

We are also subject to various laws around the world that govern interactions with our customers as healthcare professionals or government officials. The laws govern different interactions and may include: prohibiting improper influence of or payments to healthcare professionals and government officials; setting out rules for when and how to engage healthcare professionals as our vendors; requiring price reporting regulations; requiring marketing of our products within the regulatory approval (e.g., on label) promotion, sale and marketing of our products and services; the importing and exporting of our products; the operation of our facilities and distribution of our products; and disclosure of payments to healthcare professionals and entities. As we expand our operations footprint, countries to which we sell and invest in new business models, compliance with applicable laws becomes more complex and the general trend is toward increasingly stringent oversight and enforcement.

Initiatives sponsored by government agencies, legislative bodies, and the private sector to limit the growth of healthcare expenses generally are ongoing in markets where we do business. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business.

Our customers are healthcare providers that may be reimbursed by state or federal funded programs such as Medicaid, a foreign national healthcare program, or private pay insurance, each of which may offer some degree of oversight. As we expand our customer base and product offering, it is increasingly possible that there will be new opportunities to seek reimbursement from public and private payors for services that include our products, and additional laws or regulatory enforcement requirements may apply now or in the future. Also, as a medical device manufacturer and seller, we are subject to transparency reporting laws (also known as sunshine laws) that in certain countries and U.S. States require us to report transfers of value to healthcare professionals that perform services or receive other items from us (e.g., meals, travel, branded promotional or educational items, or other benefits of value). Many government agencies, both domestic and foreign, have increased their mining of this data and have used this data to drive enforcement activities with respect to healthcare providers and companies in recent years. Enforcement actions and associated efforts to respond or defend against such actions can be expensive, and any resulting findings carry the risk of significant civil and criminal penalties.

In addition, we must comply with numerous data protection and data governance laws that now do or soon will regulate or restrict cross border data transfers, such as in the EU, Switzerland, U.S. Federal and States, Brazil, China, Japan, Korea, and other countries. In the U.S., we may be required to comply with final regulations implementing amendments to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the associated HIPAA Security Rule, and are in the same position as other companies working to ensure compliance with new State Privacy laws coming into effect in 2023, such as California, Virginia, Colorado and Connecticut. In the EU, we must comply with the General Data Protection Regulation, which serves as a harmonization of European data-privacy law and the Swiss Federal Act on Data Protection, where we have our EMEA headquarters. In LATAM markets, we must comply with Brazil's Lei Geral de Proteção de Dados.

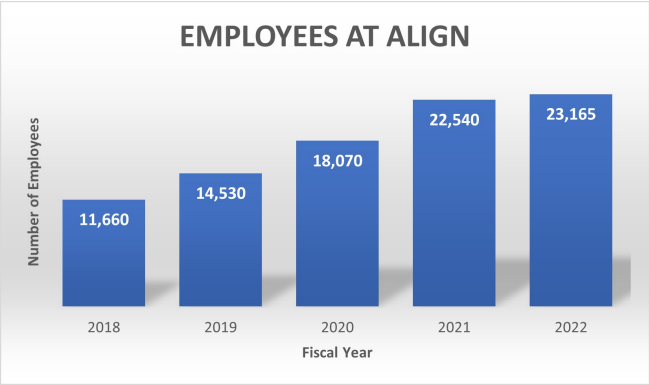
We also have cybersecurity policies to protect confidential personal information and confidential company information. We have internal monitoring and detection systems to safeguard against cyber attacks. We have implemented a security awareness and phishing program to educate our users about the importance of cybersecurity. We evaluate products to ensure compliance with cybersecurity regulations. We have established a business resiliency program and perform regular backups of our critical IT systems to protect against business interruption. In addition, we periodically scan our external environment for vulnerabilities, perform annual external penetration tests and engage an independent third party to assess effectiveness of our security practices for critical IT systems. We also have cybersecurity and other forms of insurance coverage related to a breach event covering expenses for notification, credit monitoring, investigation, crisis management, public relations and legal advice.

Information regarding risks associated with data security and privacy may be found in *Item 1A* of this Annual Report on Form 10-K under the heading "*Risk Factors*."

Human Capital

We believe our culture and commitment to employees provide unique value that benefits Align, its stockholders and the communities and other stakeholders we serve. Every employee, and every job, is important to our success and helps us achieve our purpose of transforming smiles and changing lives. Align is committed to building a workforce of diverse cultural backgrounds and life experiences. Fostering a culture of dignity, integrity, open dialogue, open-mindedness, compassion, fairness, recognition, and shared goals allows us to attract and retain the best talent, which has ultimately led to the growth and success of our company.

As of December 31, 2022, we had approximately 23,165 employees, an increase of approximately 3% and 28% over December 31, 2021, and December 31, 2020, respectively. The number of employees for each of the last five years and our employees' roles as of December 31, 2022 are as follows:



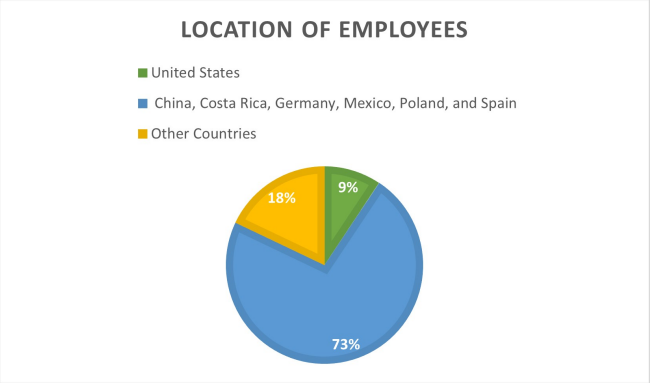
We are a global organization with the majority of our employees in direct-labor roles in our manufacturing and clinical treatment planning facilities. Set forth in the following paragraphs are some of the most important elements of our culture and commitment to our employees.

Governance. Our commitment to improving the lives of our employees and the communities in which we live and work, including conducting our business ethically, responsibly and transparently through open and clear disclosures that allow us and others to hold us accountable, begins with our Board of Directors ("Board") and management team. They set the tone for our organization by establishing and clearly communicating our core values of Agility, Customer and Accountability that inform our culture. Our Global Code of Conduct ("Code") and quality policies are designed to enable us to operate with integrity and deliver superior treatment outcomes and experiences to patients. We seek to create an environment that values the health, safety and well-being of our teams, and we work to equip them with the knowledge and skills to serve our business and develop in their careers. We believe that by effectively managing our business with these values as the foundation, we will drive long-term value for our stockholders and all stakeholders.

As part of our Board's commitment to our environmental, social and governance ("ESG") efforts, the Board previously delegated ESG oversight responsibility to our Nominating and Governance Committee. The evolution of our ESG programs was furthered in 2022 when our Board amended the charter of our Compensation Committee to specifically include oversight responsibilities of all human capital management strategies, programs and policies in addition to its oversight of diversity, equity and inclusion initiatives. In doing so, the Board deemed it important to rename the committee to the Compensation and Human Capital Committee in recognition of its additional human capital management oversight responsibilities.

The Compensation and Human Capital Committee regularly reviews and discusses key performance indicators regarding employee and human capital that allow it to more fully monitor trends involving issues such as our total headcount, recruiting, attrition, career development, diversity, compensation, benefits, and other measures of employee engagement and interest to management and the committee.

Diversity. Fostering diversity and encouraging inclusion and belonging in the workplace makes Align a more welcoming and enjoyable place to work. Our products and services are used broadly across age groups, gender identities, races, ethnicities, and cultures, so we aim to build a workforce that optimally reflects this diversity. We believe our success continues to be driven by our focus on integrating and welcoming employees of all different backgrounds, orientations, beliefs, perspectives and capabilities into our workforce. Our approximately 23,165 employees bring a positive mix of ethnic and culturally diverse backgrounds to the more than 40 different countries in which we operate.



Our management team is comprised of diverse individuals from varying countries and nationalities and who are committed to promoting and encouraging the health and well-being of our employees at work, at home and in society in general. We were selected by Untapped, a diversity recruiting platform, for having one of the Top Internship Programs of 2022. Untapped created a list of 75 top programs at companies that provide quality internship experiences, career advancement opportunities, an inclusive and diverse work environment, and significant growth potential. We were recognized for focus and dedication to diversity, equality, inclusion, and belonging.

Our work culture is designed to create financial, health, career and personal benefits for our employees and organization. We sponsor diverse and cultural recognition events to increase awareness of inclusion and diversity, including its importance in creating an environment where every employee can thrive.

We also sponsor employee resource groups based on shared characteristics or life experiences which are open to all employees, including those who do not directly identify with other members but are passionate in supporting the group's members in creating an educated, supportive and inclusive culture.

Talent Recruitment and Engagement. We employ a variety of career development, employee benefits, compensation and other policies and programs designed to attract, develop, and retain employees. We focus on building a talent pipeline that nurtures those early in their careers, encourages continuous learning and growth, and incentivizes employees to stay and contribute to our success over the long term. Our programs include early recruitment at high schools and universities, initiatives such as internships, co-ops, apprenticeships, and training programs, quarterly performance management check-ins focused on individual goals and commitment to values and conducting regular employee surveys to build trust and strengthen relationships.

Our efforts have resulted in numerous awards for our positive work environment and culture. In 2022 alone, we were recognized by:

- Great Places to Work and Best Places to Work based on our employee-validated great workplaces in the following countries - Brazil, Costa Rica, Germany, India, Italy, Poland, Singapore, Taiwan, Thailand, Vietnam - as well as in Raleigh, North Carolina
- 100 Best Companies to Work for in Israel by CofaceBdi
- Computerworld Best Place to Work in IT, based on its survey of organizations across the U.S. to identify those that provide the best benefits and amenities for IT professionals
- AmCham Cares Distinction Award Recipient in Singapore based on our volunteer and fundraising campaigns

We believe it is imperative to provide a vibrant employee experience and we value our employees' collective voices. Accordingly, we conduct employee surveys to collect employee feedback critical to improving our culture. The process serves as a wellness check for us as the surveys cover a broad variety of topics including engagement, inclusion, development, leadership, compliance, alignment and enablement. Our response rates to our annual surveys are consistently high, reflecting strong engagement by our global employees. In 2022, our global employee participation was 89% of eligible employees. We have used information learned from our surveys to improve the way our employees experience us. Examples of the improvements we have made as a result of employee feedback include the design of our hybrid return to office approach, increased career development training opportunities, and a pilot program that allows CAD designers to learn new skills that provide potential pathways to software and operations engineering, cybersecurity and quality/regulatory engineering.

Training and Professional Development. Training is an integral part of developing and retaining our employees and creating a culture of leadership within the Company.

Training at Align begins with our Code and our strong commitment to ethical business practices in all aspects of our operations. Every employee and contractor is required to review the Code and confirm they understand it. We routinely reference the Code in presentations and as part of everyday operations.

As a further part of our standard onboarding program, we train employees on important environmental health and safety topics to protect them and our environment as we operate our business. As a general practice, employees are trained to perform their jobs in accordance with any and all applicable statutory and regulatory requirements and that training is routinely re-administered, updated and refreshed.

At Align, we believe employees learn best when skills development is driven by the changing and immediate needs of our employees and where all employees are empowered to take action and ownership of their careers. We also believe learning should be relevant and actionable as well as rooted in our purpose and values. Align University Online enables our global employee population to access a diverse portfolio of approximately one thousand self-directed courses in up to 80 languages. We also offer a full suite of custom leadership development programs, beginning with aspiring leaders, continuing with managers and directors, and culminating with executive development opportunities. In 2022, we introduced Voyage, Align's approach to career development encouraging employees to think differently about career growth by challenging them to be intentional in planning their development, learning from others, practicing reflection, and embracing a growth mindset. At the end of 2022, 65% of Align employees had completed at least one professional development opportunity.

Compensation and Benefits. Our commitment to our employees starts with benefit and compensation programs that reflect the value and the contributions our employees make. In addition to competitive base pay, we offer an assortment of benefits that vary by country, including performance-base variable compensation programs, health and welfare benefit plans, retirement planning services and benefits, holiday and leave policies, equity participation programs such as our Incentive Plan and Employee Stock Purchase Plan, and charitable and community service opportunities. Besides these, we also offer discounts to our employees and their dependents when they undergo Invisalign treatment.

We are furthermore committed to pay equity practices. We exceed minimum pay requirements for our manufacturing personnel and we regularly review our pay equity practices globally and locally so that we can appropriately address discrepancies.

Health, Wellness and Safety. Our employees are essential to us as a business and their health and well-being is critical to our success and their continuing achievements. Our objective is to prevent injuries and occupational diseases by focusing first and foremost on creating and maintaining environments that are safe. We therefore offer a wide variety of robust programs and initiatives designed to promote the overall health and welfare of all our employees and their families. It is our responsibility to support the health and well-being of our employees. Every year, we have a month dedicated to well-being, called Month of Wellness, which is a worldwide movement fostering employee health. Throughout the Month of Wellness, employees participate in a variety of activities such as informational sessions and health fairs and receive useful resources aligned to our wellness pillars - mental resilience, physical well-being and healthy living, social/family connections, and financial wellness. This provides employees with a variety of meaningful ways to embrace wellness and well-being through mindfulness, meditation, nutrition and mental wellness activities, exercise, hikes, yoga, volunteer activities, financial education sessions, social events and stress management.

We have environmental, health, safety and sustainability personnel who are responsible for ensuring health and safety programs and processes are maintained and effective at each of our locations. Major worksites, such as our aligner fabrication sites, and large offices have dedicated Environmental Health and Safety ("EHS") departments that ensure health and safety programs are maintained while contributing Best Management Practices ("BMP") and general input to corporate-wide programs. Each EHS department is responsible for ensuring all employees at their location are properly trained on various EHS topics and at the appropriate frequencies. A training suite is determined for each employee depending on their responsibilities and function modeled off of ISO 45001.

Community. We actively encourage employees to support local charitable organizations by providing opportunities for volunteerism, team building, and donation and matching programs. In 2022, our employees continued to make us proud through their generosity and dedication, especially during our annual Month of Smiles initiative in October where we encourage our employees to make a difference individually and as teams through volunteer activities, charitable donations, fundraising, and intentional acts of goodness. In addition, through our Align Foundation, we support organizations whose visions closely align with our mission to improve smiles, supporting and educating teens, and empowering our customers through partnerships with learning institutions and foundations. Below are some of our key community initiatives in 2022:

- In honor of our 25th anniversary, we donated $250,000 to Junior Achievement Worldwide, an organization that delivers hands on, immersive learning in work readiness, financial health, entrepreneurship, sustainability, STEM, economics, and more. In addition, we held several volunteer activities with Junior Achievement.

- Since 2013 we have been a proud supporter of Operation Smile, a global medical nonprofit providing hundreds of thousands of free surgeries for people born with cleft lips and cleft palates in low- and middle-income countries. As of December 31, 2022, we had donated more than $2.5 million to Operation Smile.

- For 15 years we have supported America's ToothFairy, an organization with a mission to ensure underserved children in the United States have access to dental care and learn about oral health by supporting nonprofit clinics and community partners. As of December 31, 2022, we have provided almost $2 million for the foundation's operational expenses and children's oral health programs.

We also provide product donations to the dental community to help patients in need of healthy, beautiful smiles. For more information on our charitable and community efforts, please refer to the Corporate Social Responsibility portion of our corporate website located at *https://www.aligntech.com/about/corporate_social_responsibility*.

Available Information

Our corporate website is *www.aligntech.com*, and our investor relations website is *http://investor.aligntech.com*. The information on or accessible through our websites is not part of this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our proxy statement on Schedule 14A for our annual stockholders' meeting and amendments to such reports are available, free of charge, on our investor relations website as soon as reasonably practicable after we electronically file or furnish such material with the SEC. Further, the SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at *http://www.sec.gov*.

Information about our Executive Officers

The following table sets forth certain information regarding our executive officers as of February 27, 2023:

Name	Age	Position	Period
Joseph M. Hogan 	65	*President and Chief Executive Officer of Align* • Chief Executive Officer of ABB • Chief Executive Officer of GE Healthcare	2015-Present 2008-2013 2000-2008
John F. Morici 	56	*Chief Financial Officer and Executive Vice President, Global Finance of Align* • Chief Financial Officer and Senior Vice President, Global Finance of Align • Chief Financial Officer of Align • Executive Vice President and Managing Director of NBC Universal • Chief Financial Officer/Chief Operating Officer of NBC Universal • Senior Vice President and Chief Financial Officer of NBC Universal	2022-Present 2018-2022 2016-2018 2014-2016 2011-2014 2007-2011
Julie Coletti 	55	*Executive Vice President, Chief Legal and Regulatory Officer of Align* • Senior Vice President, Chief Legal and Regulatory Officer of Align • Vice President, Associate General Counsel, Strategic Commercial Affairs of Align • Vice President, Global General Counsel and Chief Compliance Officer of Danaher • Vice President, Chief Legal Officer and Corporate Secretary of Bayer HealthCare's MEDRAD/Radiology and Interventional Division	2022-Present 2019-2022 2018-2019 2013-2017 2007-2013
Stuart Hockridge 	51	*Executive Vice President, Global Human Resources of Align* • Senior Vice Present, Global Human Resources of Align • Vice President, Global Human Resources of Align • Vice President of Talent of Visa	2022-Present 2018-2022 2016-2018 2013-2016
Emory M. Wright 	53	*Executive Vice President, Global Operations of Align* • Senior Vice President, Global Operations of Align • Vice President, Operations of Align • Various roles at Align including Vice President, Manufacturing	2022-Present 2018-2022 2007-2018 2000-2007

Item 1A. Risk Factors.

The following discusses some of the risks that may affect our business, results of operations and financial condition. You should carefully review this section, as well as our consolidated financial statements and notes thereto and other information appearing in this Annual Report on Form 10-K, for important information regarding these and other risks that may affect us. The order we have chosen to list the risks below or the sections in which we have identified them should not be interpreted to mean we deem any risks to be more or less important or likely to occur or, if any do occur, that their impact may be any less significant than others. These risk factors should be considered in connection with evaluating the forward-looking statements contained in this report because they could cause our actual results and conditions to differ materially from those statements. Before you invest in Align, you should know that investing involves risks, including those described below. The risks below are not the only ones we face. If any of the risks actually occur, our business, financial condition and results of operations could be negatively affected, the trading price of our common stock could decline, and you may lose all or part of your investment.

Summary of Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows, and prospects. These risks are discussed more fully below and include, but are not limited to:

Macroeconomic and External Risks

- Global and regional economic conditions
- Major health crises
- Political events, international disputes, war and terrorism
- Natural disasters

Business and Industry Risks
- Changes in demand for our products
- Increased competition
- Failure of our new products, or changes to our existing products, to attract or retain consumers or generate revenue
- Our ability to successfully integrate our acquisitions

Operational Risks
- Business disruptions
- Predicting demand
- Availability of supplies
- Shipping delays
- Personnel development and retention
- Effectiveness of marketing and our ability to attract consumers

Legal, Regulatory and Compliance Risks
- Government investigations, enforcement actions, and settlements
- Our ability to comply with laws and regulatory and legislative mandates or guidance
- Privacy, cybersecurity and data protection
- Litigation, including class action lawsuits

Intellectual Property Risks
- Our ability to obtain, maintain, protect, and enforce our intellectual property rights

Financial, Tax and Accounting Risks
- Impairment of our goodwill
- Compliance with accounting, financial reporting, and tax laws
- Management of our stock plans
- Volatility of our stock

Macroeconomic and External Risks

Our operations and financial performance depend on global and regional economic conditions. Inflation, fluctuations in currency exchange rates, changes in consumer confidence and demand, and weakness in general economic conditions and threats, or actual recessions, have and could in the future materially affect our business, results of operations, and financial condition.

Macroeconomic conditions impact consumer confidence and discretionary spending, which can adversely affect demand for our products. Consumer spending habits are affected by, among other things, inflation, fluctuations in currency exchange rates, weakness in general economic conditions, threats or actual recessions, pandemics, wars and military actions, levels of employment, wages, debt obligations, discretionary income, interest rates, volatility in capital, and consumer confidence and perceptions of current and future economic conditions. Changes and uncertainty can, among other things, reduce or shift spending away from elective treatments and procedures, drive patients to purchase orthodontic treatments that may cost less than our Invisalign treatment options, result in a decrease in the number of overall orthodontic and dental case starts, reduce patient traffic in dentists' offices or reduce demand for dental services generally. Further, decreased demand for dental services can cause dentists and labs to postpone investments in capital equipment, such as intraoral scanners and CAD/CAM equipment and software. The recent declines in, or uncertain economic outlooks for, the U.S., Chinese, European and certain other international economies has and may continue to adversely affect consumer and dental practice spending. The increase in the cost of fuel and energy, food and other essential items along with climbing interest rates could reduce consumers' disposable income, resulting in less discretionary spending for products like ours. Decreases in disposable income and discretionary spending or change in consumer confidence and spending habits has and may continue to adversely affect our revenues and operating results.

Inflation continues to adversely impact spending and trade activities and we are unable to predict the impacts of higher inflation on global and regional economies. Higher inflation has also increased domestic and international shipping costs, raw material prices, and labor rates, which could adversely impact the costs of producing, procuring and shipping our products. Our ability to recover these cost increases through price increases may continue to lag, resulting in downward pressure on our operating results. Attempts to offset cost increases with price increases may reduce sales, increase customer dissatisfaction or otherwise harm our reputation. Further, we are unable to predict the impact of efforts by central banks and federal, state and local governments to combat elevated levels of inflation. If their efforts to reduce inflation are too aggressive, they may lead to a recession. Alternatively, if they are insufficient or are not sustained long enough to lower inflation to more acceptable levels, consumer spending may be adversely impacted for a prolonged period of time. Any of these events could materially affect our business and operating results.

We have international operations and sales outside the U.S. We earn a large portion of our total revenues from international sales generated through our foreign direct and indirect operations and we expect to increase our sales and presence outside the U.S., particularly in markets we believe have high-growth potential. Moreover, we perform most of our key

production steps in locations outside of the U.S. For instance, we perform our digital treatment planning and aligner fabrication in multiple international locations, including large-scale operations in Mexico, Costa Rica, Poland, Japan and China. Additionally, we maintain significant global sales and marketing operations in Switzerland, Singapore and China, along with research and development operations globally, including in the U.S., Spain, Israel, Armenia and Germany. Our reliance on international operations and sales exposes us to fluctuations in foreign currencies that may adversely impact our business or results of operations. Although the U.S. dollar is our reporting currency, a growing portion of our net revenues and net income are generated in foreign currencies. While we utilize forward contracts to reduce the adverse earnings impact from the effect of exchange rate fluctuations on certain assets and liabilities, our hedging strategies may not be successful, and currency exchange rate fluctuations have and could continue to have a material adverse effect on our operating results and cash flows. In addition, our foreign currency exposure on assets, liabilities and cash flows that we do not hedge have and could continue to have a material impact on our financial results in periods when the U.S. dollar significantly fluctuates in relation to foreign currencies.

Our business could be impacted by major public health issues, including pandemics, and our business has been and continues to be materially affected by the global and regional spread of COVID-19.

Major public health issues, including pandemics such as the spread of COVID-19, have adversely affected, and could in the future materially affect, our business due to their impact on the global economy and regional economies, demand for consumer products, the imposition or removal of public safety measures. Public health concerns may also limit the movement of products between regions, disrupt or delay supply chains and sales and distribution channels, resulting in interruptions of the supply of products. While we maintain insurance coverage for certain types of losses, such insurance coverage may be insufficient to cover all losses that may arise.

COVID-19 has created significant, widespread and unprecedented volatility, uncertainty, and economic instability, disrupting broad aspects of global and regional economies, our operations and the businesses of our customers and suppliers. Many of these effects continue to varying degree as variants of COVID-19 and outbreaks globally or regionally continue to harm recovering consumer confidence. Therefore, comparing our financial results for the reporting periods of 2022 to the same reporting periods of 2021 or earlier may not be a useful means by which to evaluate the health of our business and our results of operations.

As a result of outbreaks of COVID-19 and its variants, customer demand and doctor availability has been inconsistent and difficult to predict. Although the practices of the doctors, dental service organizations and labs that are our principal customers have largely reopened following the initial outbreak of COVID-19 in 2020, many continue to operate at less than pre-pandemic capacities. For example, in China the impact of widespread population lockdowns under the country's zero tolerance policies was more pronounced in 2022, leading to the complete closure of dental offices in major metropolitan and other areas for extended periods of time. Conversely, the reversal of China's zero tolerance policies has resulted in a significant increase in infections that may impact consumer and doctor demand in 2023. These fluctuations are currently and have previously adversely impacted our results of operations and are expected to continue to impact our results, particularly in the near term.

The effects of the pandemic continue to linger and evolve and we cannot predict future direct and ancillary impacts on our business or results of operations, although they may be material to our business as well as the businesses of our customers, suppliers and economic activity generally.

The COVID-19 pandemic has impacted virtually all aspects of our business and society. It has exacerbated many pre-existing risks to our business by making them more likely to occur or more impactful when they do occur. Accordingly, you should consider the risks described in this risk factor in addition to, and not in lieu of, the risks described elsewhere throughout these risk factors.

Our business could be impacted by political events, trade and other international disputes, war, and terrorism, including the military conflict between Russia and Ukraine.

Political events, trade and other international disputes, war, and terrorism could harm or disrupt international commerce and the global economy and could have a material effect on our business as well as our customers, suppliers, contract manufacturers, distributors, and other business partners.

Political events, trade and other international disputes, wars, and terrorism can lead to unexpected tariffs or trade restrictions, which could adversely impact our business. Tariffs increase the cost of our products and the components and raw materials to make them. These increased costs could adversely impact our gross margin and make our products less competitive or reduce demand. Countries could also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain and limit our ability to offer products and services. These measures could require us to take various actions, including changing suppliers or restructuring business relationships. Complying with new or changed trade restrictions is expensive, time-consuming and disruptive to our operations. Such restrictions can be announced with little or no advance notice and we may be unable to effectively mitigate the adverse impacts

of such measures. If disputes and conflicts escalate in the future, actions by governments in response could be significantly more severe and restrictive and could materially affect our business.

Political unrest, threats, tensions, actions and responses to any social, economic, business, geopolitical, military, terrorism, or acts of war involving key commercial, development or manufacturing markets such as China, Mexico, Israel, Europe, or other countries could materially impact our international operation. For example, our employees in Israel could be obligated to perform annual reserve duty in the Israeli military and be called for additional active duty under emergency circumstances. If any of these events or conditions occur, the impact to us, our employees and customers is uncertain, particularly if emergency circumstances, armed conflicts or an escalation in political instability or violence disrupts our product development, data or information exchange, payroll or banking operations, product or materials shipping by us or our suppliers and other unanticipated business disruptions, interruptions and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure.

The military conflict between Russia and Ukraine has materially adversely impacted global economies, and has materially impacted our global and regional operations. Governments including the U.S., United Kingdom, and those of the European Union have imposed export controls on certain products and financial and economic sanctions on certain industry sectors and parties in Russia which has triggered retaliatory sanctions by the Russian government and its allies. Our commercial operations have been impacted by the conflict and if we fail to support existing customers, we may frustrate those customers, harm our reputation, and be subject to regulatory action in Russia. Additionally, a majority of our research and development personnel in Russia relocated to locations outside of Russia in 2022. Whether they remain in their new locations over the long-term remains unknown. If we are unable to retain key skilled personnel from where they have relocated, or we are unable to quickly replace such personnel with individuals of equivalent technical expertise and qualifications, our business and financial condition could be materially effected.

The outcome and future impacts of the Russia and Ukraine conflict remain highly uncertain, continue to evolve and may grow more severe the longer the military action and sanctions remain in effect. Moreover, this conflict and existing and future sanctions may have broad and pervasive impacts to the global and regional economies and our operations, heightening and affecting many of the other risks described elsewhere throughout these risk factors, any of which could materially and adversely affect our business and results of operations. Such risks include adverse effects on general economic and political conditions such as inflation, supply chain and trade disruptions, and reduced consumer spending; disruptions to our IT systems, including through network failures, malicious or disruptive software, or cyberattacks; energy shortages or rationing that may adversely impact our manufacturing facilities; rising fuel and/or rising costs of producing, procuring and shipping our products; our exposure to foreign currency exchange rate fluctuations; and constraints, volatility or disruption in the financial markets. We may not be successful in our efforts to mitigate the negative impacts of the conflict, particularly the longer sanctions and retaliatory sanctions remain in effect. How we respond to the conflict may also subject us to risk. The resumption of sales in Russia or our decision to continue supporting our personnel and existing customers in Russia may result in reputational harm or boycotts of our products that could impact our sales and operations inside and outside of Russia or subject us to litigation for which we may be found liable in courts or other tribunals in Russia or elsewhere. Moreover, production could be impaired should hostilities spread to other countries such as Poland, where our newest aligner fabrication facility is located.

We have no way to predict the progress or outcome of the conflict in Ukraine or the reactions by governments, businesses or consumers. A prolonged conflict, intensified military activities or more extensive sanctions impacting the region and the resulting economic impact could have a material effect on our business, results of operations, financial condition, liquidity, growth prospects and business outlook.

Our operations may be impacted by natural disasters, which may become more frequent or severe as a result of climate change, and may adversely impact our business and operating results as well as those of our customers and suppliers.

Natural disasters can impact us and our customers, as well as suppliers critical to our operations. Natural disasters include earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, and other extreme weather conditions that can cause deaths, injuries, and critical health crises, power outages, restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures, materials scarcity, price volatility and other ramifications. Climate change is likely to increase both the frequency and severity of natural disasters and, consequently, risks to our business and operations. Our digital dental modeling and certain of our customer facing operations are primarily processed in our facilities located in Costa Rica. Our aligner molds and finished aligners are fabricated in China, Mexico and Poland. Our locations in Costa Rica and Mexico as well as others are in earthquake and hurricane zones and may be subject to other natural disasters. Moreover, a significant portion of our research and development activities are located in California, which suffers from earthquakes, periodic droughts, heat waves, flooding, power shortages and wildfires. If there is a natural disaster in a region where one of these facilities is located, our employees could be impacted, our research could be lost, and our ability to create ClinCheck treatment plans, respond to customer inquiries or manufacture and ship our aligners or intraoral scanners could be compromised which could result in our customers experiencing significant product and services delays.

The effects of climate change on regional and global economies could change the supply, demand or availability of sources of energy or other resources material to our products and operations and affect the availability or cost of natural resources and goods and services on which we and our suppliers rely.

Business and Industry Risks

Demand for our products may not increase or may decrease due to resistance to non-traditional treatment methods, which could have a material impact on our business and operating results.

Invisalign treatment represents a significant change from traditional metal wires and brackets orthodontic treatment, and customers and consumers may not find it cost-effective or preferable to traditional treatment. For instance, a number of dental professionals continue to believe the Invisalign treatment is appropriate for only a limited percentage of patients. Increased market acceptance of our products depends in part upon the recommendations of dental professionals, as well as other factors including efficacy, safety, ease of use, reliability, aesthetics, and price compared to competing products and treatment methods. If demand for our products fails to increase, including due to resistance to nontraditional treatment methods, this could materially affect our business and operating results.

Our net revenues depend primarily on our Invisalign system and iTero scanners and any decline in sales or average selling price of these products may adversely affect net revenues, gross margin and net income.

Our net revenues remain largely dependent on sales of our Invisalign system of clear aligners and iTero intraoral scanners. Of the two, we expect net revenues from the sale of the Invisalign system, primarily our comprehensive products, will continue to account for the majority of our net revenues, making the continued and widespread acceptance of the Invisalign system by orthodontists, GPs and consumers critical to our future success. Our iTero business also contributes a material percentage of our overall net revenues. Our CAD/CAM software solutions are important to the continuing evolution of our Align Digital Platform and our business overall. Our operating results could be harmed if:

- orthodontists and GPs experience a reduction in consumer demand for orthodontic services;
- consumers are unwilling to adopt Invisalign system treatment as rapidly or in the volumes we anticipate and at the prices offered;
- orthodontists or GPs choose to continue using wires and brackets or competitive products rather than the Invisalign system or the rates at which they utilize the Invisalign system fail to increase or increase as rapidly as anticipated;
- sales of our iTero scanners decline or fail to grow sufficiently or as anticipated;
- the growth of CAD/CAM solutions does not produce the results anticipated; or
- if the average selling price of our products declines.

The average selling prices of our products, particularly our Invisalign system, are influenced by numerous factors, including the type and timing of products sold (particularly the timing of orders for additional clear aligners for certain Invisalign products) and foreign exchange rates. In addition, we sell a number of products at different list prices which may differ based on country. Our average selling prices for our Invisalign system and iTero scanners have been impacted in the past and may be adversely affected again in the future if:

- we introduce new or change existing promotions, general or volume-based discount programs, product or services bundles, or consumer rebate programs;
- participation in any promotions or programs unexpectedly increases or decreases or drives demand in unexpected and material ways;
- our geographic, channel, or product mix shifts to lower priced products or to products that have a higher percentage of deferred revenue;
- we decrease prices on one or more products or services in response to increasing competitive pricing pressures;
- we introduce new or change existing products or services, or modify how we market or sell any of our new or existing products or services;
- governments impose pricing regulations such as the volume-based procurement regulations in China; or
- estimates used in the calculation of deferred revenue differ from actual average selling prices.

If our average selling prices decline, our net revenues, gross margin and net income may be adversely affected.

Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that may introduce new technologies or products in the future and customers who alone or with others create orthodontic appliances and solutions or other products or services that compete with us.

The dental industry is in a period of immense and rapid digital transformation involving products, technologies, distribution channels and business models. While solutions such as our Invisalign system, iTero scanners and CAD/CAM

software facilitate this transition, whether our technologies will achieve market acceptance and, if adopted, whether and when they may become obsolete, remains unclear.

Currently, the Invisalign system competes primarily against traditional metal wires and brackets and increasingly against clear aligners manufactured and distributed by new market entrants and manufacturers of traditional wires and brackets, both within and outside the U.S., and from traditional medical device companies, laboratories, startups and, in some cases, doctors and DSOs themselves. The number and types of competitors are diverse and growing rapidly. They vary by segment, geography, and size, and include new and well-established regional competitors in dental markets, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. Our competitors also include direct-to-consumer ("DTC") companies that provide clear aligners using a remote business model requiring little or no in-office care from trained and licensed doctors, and doctors and DSOs who can manufacture custom aligners in their offices using 3D printing technology. Large consumer product companies may also start supplying orthodontic products.

The manipulation and movement of teeth and bone is a complex and delicate process with potentially painful and debilitating results if improperly performed or monitored. Accordingly, we deliver our Invisalign system solutions primarily through trained and skilled doctors. The Invisalign system requires a doctor's prescription and an in-person physical examination of the patient's dentition before beginning treatment; however, with the advent of DTC providers, there has been a shift away from traditional dental practices that may impact our primary selling channels. Doctors and DSOs are sampling alternative products and taking advantage of competitive promotions and sale opportunities. In addition, we face competition from companies that introduce new technologies and we may be unable to compete with these competitors or they may render our technology obsolete or economically unattractive. If we are unable to compete effectively with existing products or respond effectively to any new technologies, our business could be harmed.

Our iTero intraoral scanner can be used to start clear aligner therapy, as well as other dental procedures, including restorative, implant planning and dentures, and also functions as a diagnostic tool. The iTero intraoral scanner competes with polyvinyl siloxane ("PVS") impressions that doctors use for clear aligner therapy or other dental procedures, as well as other intraoral scanners. It also competes with traditional bite wing 2D dental x-rays for detecting interproximal caries. If we are unable to compete effectively with these existing products or respond effectively to new technologies, our Systems and Services segment could be harmed.

To stimulate product and services demand, we have a history of offering volume discounts, price reductions and other promotions to targeted customers and consumers. Whether or not successful, these promotional campaigns have had and may in the future have unexpected and unintended consequences, including reduced gross margins, profitability and average selling prices, net revenues, volume growth, and net income.

We cannot assure that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material effect on our business, results of operations and financial condition.

Our success depends on our ability to successfully develop, introduce, achieve market acceptance of, and manage new products and services.

Our success depends on our ability to profitably and quickly develop, manufacture, market, obtain and maintain regulatory approval or clearance of new products and services along with improvements to existing products and services. There is no assurance we can successfully develop, sell and achieve market acceptance of our new or improved products and services. The extent of, and rate at which, new products or services may achieve market acceptance and penetration is a function of many variables, including our ability to:

- successfully predict and timely innovate and develop new technologies and applications with the features and functionality customers desire or expect;
- successfully and timely obtain regulatory approval or clearance of new and improved products or services from government agencies such as the FDA and analogous agencies in other countries;
- cost-effectively and efficiently develop, manufacture, quality test, dispose of, and sell new or improved products and services offerings;
- properly forecast the amount and timing of new or improved product and services demand;
- allocate our research and development funding to products and services with higher growth prospects;
- ensure compatibility of our technology, services and systems with those of our customers;
- anticipate and rapidly innovate in response to new competitive products and services offerings and technologies;
- differentiate our products and product offerings from our competitors as well as other products in our own portfolio and successfully articulate the benefits to our customers;

- cost effectively manage any increased expense of developing, testing, manufacturing and marketing localized versions of our products internationally;
- manage the impact of nationalism or initiatives to encourage the purchase or support of domestic vendors, which can influence customers not to purchase products from, or collaborate to promote interoperability of products with foreign companies;
- qualify for third-party reimbursement for procedures involving our products; and
- encourage customers to adopt new technologies and provide the needed technical, sales and marketing support to make new product and services launches successful.

If we fail to accurately predict customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development that does not lead to significant revenues. Even if we successfully innovate and develop new products and product improvements, we may incur substantial costs doing so and our profitability may suffer. It may be difficult to gain market share and acceptance for new or improved products. Introduction and acceptance of any products and services may take significant time and effort, particularly if they require doctor education and training to understand their benefits or doctors choose to withhold judgment on a product until patients complete their treatments. For instance, it can take up to 24 months or longer to complete treatment using our Invisalign system.

In addition, we periodically introduce new business and sales initiatives to meet customers' needs and demands. In general, our internal resources support these initiatives without clear indications they will prove successful or be without short-term execution challenges. Should these initiatives be unsuccessful, our business, results of operations and financial condition could be materially impacted.

We have in the past and may again in the future invest in or acquire other businesses, products or technologies which may require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.

Periodically, we may acquire, or make investments in, companies, products or technologies. Alternatively, we may be unable to find suitable investment or acquisition targets and we may be unable to complete investments or acquisitions on favorable terms, if at all. If we make investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals or desired synergies, and investments or acquisitions we complete could be viewed negatively by our customers, securities analysts and investors. Moreover, to the extent we make strategic investments, the companies in which we invest may fail or we may ultimately own less than a majority of the outstanding shares of the company and be outvoted on critical issues that could harm us or the value of our investment.

Additionally, as an organization we do not have a history of significant acquisitions or integrating their operations and cultures with our own. As such, we are subject to various risks when making a strategic investment or acquisition which could materially impact our business or results of operations, including that we may:

- fail to perform proper due diligence and inherit unexpected material issues or assets, including IP or other litigation or ongoing investigations, accounting irregularities or improprieties, bribery, corruption or other compliance liabilities;
- fail to comply with regulations, governmental orders or decrees;
- experience IT security and privacy compliance issues;
- invest in companies that generate net losses or the markets for their products, services or technologies may be slow or fail to develop;
- not realize a positive return on investment or determine that our investments have declined in value, such that it may be necessary to record impairments such as future impairments of intangible assets and goodwill;
- have to pay cash, incur debt or issue equity securities to pay for an acquisition, adversely affecting our liquidity, financial condition or the value of our common stock. The sale of equity or issuance of debt to finance any acquisition could result in dilution to our stockholders. The occurrence of indebtedness would result in increased fixed obligations and could also include covenants or other restrictions that would impede our ability to manage our operations;
- find it difficult to implement and harmonize company-wide financial reporting, forecasting and budgeting, accounting, billing, IT and other systems due to inconsistencies in standards, internal controls, procedures and policies;
- require significant time and resources to effectuate the integration;
- fail to retain key personnel or harm our existing culture or the culture of an acquired entity;
- not realize any or all or material portions of the expected synergies and benefits of the acquisition; or
- unsuccessfully evaluate or utilize the acquired technology or acquired company's know-how or fail to successfully integrate the technologies acquired.

Moreover, opposition to one or more acquisitions could lead to negative ratings by analysts or investors, give rise to objections by one or more stockholders or result in stockholder activism, any of which could harm our stock price.

Operational Risks

Business disruptions could seriously harm our financial condition.

Our global operations have been disrupted in the past and will likely be disrupted and harmed again in the future. The occurrence of any material or prolonged business disruptions, whether internal or at key suppliers, could harm our business and results of operations, result in material losses, seriously harm our revenues, profitability and financial condition, adversely affect our competitive position, increase our costs and expenses, and require substantial expenditures and recovery time in order to fully resume operations.

When business disruptions occur, they may, individually or in the aggregate, affect our ability to provide products, services and solutions to our customers, and could cause production delays or limitations, create adverse effects on distributors, disrupt supply chains, result in shipping and distribution disruptions and reduce the availability of or access to one or more facilities. We have policies and procedures which are intended to mitigate the impact of the business disruptions and crises that we believe could be most significant, and we train employees and work with suppliers to prepare for potential disruptions. However, the design or implementation of these policies and practices may fail to adequately address particular disruptions, which could materially and adversely affect our business, financial condition and results of operations.

Our operating results have and will continue to fluctuate in the future, which makes predicting the timing and amount of customer demand, our revenues, costs and expenditures difficult.

Our quarterly and annual operating results have and will continue to fluctuate for a variety of reasons, including as a result of changing doctor and consumer product demand. In addition to the factors otherwise described herein, some of the other factors that have historically and could cause our operating results to fluctuate in the future include:

- higher manufacturing, delivery and inventory costs;
- the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due;
- changes in the timing of revenue recognition and changes in our average selling prices, including as a result of the timing of receipt of product orders and shipments, product and services mix, geographic mix, product and services deferrals, the introduction of new products and software releases, product pricing, bundling and promotions, pricing for fees or expenses, modifications to our terms and conditions such as payment terms, or as a result of new accounting pronouncements or changes to critical accounting estimates including, without limitation, estimates based on matters such as our predicted usage of additional aligners;
- seasonal fluctuations, including those related to patient demographics or seasonality as well as the availability of doctors to take appointments;
- longer customer payment cycles and greater difficulty in accounts receivable collection for our international sales;
- costs and expenditures, including connection with the establishment of new treatment planning and fabrication facilities, the hiring and deployment of personnel, litigation, and the success of or changes to our marketing programs from quarter to quarter; and
- timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows.

Failing to accurately predict customer demand may cause us to have inadequate staffing, materials or storage required to manufacture our products to meet demand. If we underestimate demand, it may exceed our manufacturing capacity or that of one or more of our suppliers, we may be understaffed and we may not have sufficient materials needed for production. Specifically, our manufacturing process relies on sophisticated computer software and requires new technicians to undergo a relatively long training process, often 120 days or longer. As a result, if we are unable to accurately predict demand, we may have an insufficient number of trained technicians to ensure products are timely manufactured and delivered to meet customers' expectations, which could damage our relationships with our existing customers or harm our ability to attract new customers. Specifically, production levels for our intraoral scanner are generally forecasted based on forecasts and historic product demand and we often place orders with suppliers for materials, components and sub-assemblies ("materials and components") as well as finished products weeks or more in advance of projected customer orders.

Conversely, if we overestimate customer demand, we may lose opportunities to increase revenues and profits, we may have excessive staffing, materials, components and finished products, or capacity. If we hire and train too many technicians in anticipation of demand that does not materialize or materializes slower than anticipated, our costs and expenditures may outpace our revenues or revenue growth, harming our gross margin and financial results. Additionally, in order to secure supplies for production of products, we sometimes enter into non-cancelable minimum purchase commitments with vendors, which could impact our ability to adjust our inventory to reflect declining market demands. If product demand decreases or increases more than forecast, we may be required to purchase or lease additional or larger facilities and additional equipment, or we may be unable to fulfill customer demand in the time frames and with the quantities required, any of which may take time to

accomplish, lower our gross margin, inhibit sales or harm our reputation. Production of our Invisalign clear aligners and iTero intraoral scanners are also limited by capacity constraints due to a variety of factors, including labor shortages, shipping delays, our dependency on third-party vendors for key materials, parts, components and equipment, and limited production yields. Any or all of these problems could result in the loss of customers, provide an opportunity for competing products to gain market acceptance and otherwise harm our business and financial results and those of our business partners.

Improvements to or changes in our products may affect the demand and make demand less predictable. We routinely review inventory for usage potential, including fulfillment of customer warranty obligations and spare part requirements, and we write down to the lower of cost or net realized value the excess and obsolete inventory, which may materially affect our results of operations. For instance, periodically we announce new products, capabilities, or technologies that replace or shorten the life cycles of legacy products or cause customers to defer or stop purchasing legacy products until new products become available. These risks increase the difficulty of accurately forecasting demand for discontinued and new products as well as the likelihood of inventory obsolescence, loss of revenue and associated gross profit.

We may make business decisions that adversely affect our operating results such as modifications to our pricing policies and payment terms, promotions, development efforts, product releases, business structure or operations. Most of our expenses, such as employee compensation and lease obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations for future revenues. As a result, if our net revenues for a particular period are below expectations, we may be unable to timely or effectively reduce spending to offset any net revenues shortfall.

We are subject to operating risks, including excess or constrained capacity and operational inefficiencies, which could adversely affect our results of operations.

We are subject to operating risks, including excess or constrained capacity and pressure on our internal systems, personnel and suppliers. In order to manage current and anticipated future operations effectively, we must continually implement and improve our operational, financial and management information systems, hire, train, motivate, manage and retain employees, and ensure our suppliers remain diverse and capable of meeting growing demand for the systems, raw materials, parts and components essential to the manufacture and delivery of our products. We may be unable to balance near-term efforts to meet existing demand with future customer demand, including adding personnel, creating scalable, secure and robust systems and operations, and automating processes needed for long term efficiencies. Any such failure could have a material impact on our business, operations and prospects.

Additionally, we have established treatment planning and manufacturing facilities closer to our international customers to provide them with better experiences, improve their confidence using our products to treat patients, create efficiencies, and provide redundancy should other facilities be temporarily or permanently unavailable. Our ability to obtain and maintain regulatory clearance and certifications and equip facilities is subject to significant risk and uncertainty. If a facility is temporarily or permanently, partially or fully shut down, or if demand for our products outpaces our ability to hire qualified personnel and effectively implement systems and infrastructure, we may be unable to fulfill orders timely, or at all, which may negatively impact our financial results, reputation and overall business.

Our products and information technology systems are critical to our business. Issues with product development or enhancements, IT system integration, implementation, updates and upgrades have previously and could again in the future disrupt our operations and have a material impact on our business and operating results.

We rely on the efficient, uninterrupted and secure operation of our own complex IT systems and are dependent on key third party software embedded in our products and IT systems as well as third-party hosted IT systems to support our operations. All software and IT systems are vulnerable to damage, cyber attacks or interruption from a variety of sources. To effectively manage and improve our operations, our IT systems and applications require an ongoing commitment of significant expenditures and resources to maintain, protect, upgrade, enhance and restore existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards, increasingly sophisticated cyber threats, and changing customer preferences. Expanded remote working and increased usage of online and hosted technology platforms by us, our customers and suppliers, including teledentistry and new or expanded use of online service platforms, products and solutions such as video conferencing applications, doctor, consumer and patient apps have increased the demands on and risks to our IT systems and personnel. Moreover, we continue to transform certain business processes, extend established processes to new subsidiaries and/or implement additional functionality in our enterprise resource planning, product development, manufacturing, and other software and IT systems which entails certain risks, including disruption of our operations, such as our ability to develop and update products that are safe and secure, track orders and timely ship products, manage our supply chain and aggregate financial and operational data. Failure to adequately protect and maintain the integrity of our products and IT systems may result in a material effect on our financial position, results of operations and cash flows.

We have a complex, global iTero intraoral scanner installed base of older and newer models. These models are continually updated to add, expand or improve on existing or new features with hardware improvements, improvements to third party

components, or part repair or replacement. We have experienced hardware issues in the past and may in the future, including issues relating to manufacturing, design, quality, or safety, of which we become aware only after products or changes have been introduced into the market. We also have not been and may not be able to ensure that third party components or any changes to the foregoing will not be incompatible with, or have a negative impact on the functionality of our iTero intraoral scanners. As a result, there have been and may be widespread failures of our iTero intraoral scanners or we may experience epidemic failures of our iTero intraoral scanner to perform as anticipated. Previously, we have not been and in the future may not be prepared for, or have the infrastructure to, timely and adequately remediate or implement corrective measures for such failures, including due to our dependency on third party providers or suppliers. As a consequence, remediation has been and may be in the future time-consuming and difficult to achieve, which may materially impact our customers and our business partners, damage our reputation and result in lost business and revenue opportunities, and could be materially costly.

Additionally, we continuously upgrade and issue new releases of our products and customer facing software applications, upon which customer facing, manufacturing and treatment planning operations depend. Software applications and products containing software frequently contain errors or defects, especially when first introduced or when new versions are released. Additionally, the third-party software integrated into or interoperable with our products and services will routinely reach end of life, and as a consequence, certain models of our iTero intraoral scanners may be exposed to additional vulnerabilities, including increased security risks, errors and malfunctions that may be irreparable or difficult to repair. The discovery of a defect, error or security vulnerability in our products, software applications or IT systems, incompatibility with customers' computer operating systems and hardware configurations with a new release or upgraded version or the failure of our products or primary IT systems may cause adverse consequences, including: delay or loss of revenues, significant remediation costs, delay in market acceptance, loss of data, disclosure of financial, health or other personal information of our customers or their patients, product recalls, damage to our reputation, loss of market share or increased service costs, any of which could have a material effect on our business, financial condition or results of our operations and the operations of our customers or our business partners.

A significant portion of our clear aligner production is dependent on digital scans from our globally dispersed and decentralized installed base of iTero and third-party intraoral scanners. Failures of all or any portion of ours or third-party software or other components or systems to interoperate with iTero or third-party scanners, termination of interoperability with third-party scanners, malware or ransomware attacks, product or system vulnerabilities or defects, interference or disruptions for us, our customers, labs or other business partners in the use of our products or the transmission or processing of data needed for the use or ordering of our products, or a system outage for any reason have harmed our operations previously and in the future could affect materially and adversely our ability to accept scans, manufacture clear aligners or restorative procedures or treatments and services or otherwise service our customers which may, amongst other things, harm our sales, damage our reputation, adversely impact our strategic partners or result in litigation.

We are highly dependent on third-party suppliers, some of whom are sole source suppliers, for certain key machines, components and materials, and our business and operating results could be harmed if supply is restricted or ends, or if the price of raw materials used in our manufacturing process increases.

We are highly dependent on our supply chain, particularly manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our intraoral scanners. We maintain single supply relationships for many of these machines and materials. In particular, our CT scanning and stereolithography equipment used in our aligner manufacturing and many of the critical components for the optics of our scanners are provided by single suppliers. We rely on a single third-party manufacturer to supply key sub-assemblies for our iTero Element scanner. We purchase the vast majority of our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, from a single source. By using single suppliers for materials and manufacturing in a limited number of locations, we risk multiple supply chain vulnerabilities. For example, damage to or destruction of a facility can materially disrupt our ability to timely deliver key parts, components and materials or products or a supplier could encounter financial, operating or other difficulties, be unable to hire or maintain personnel, fail to timely obtain supplies, fail to maintain manufacturing standards or controls. To the extent any of our suppliers or others' suppliers in our supply chain are dependent on raw materials, components or other parts from Russia or Ukraine, the foregoing risks may be more likely to occur as a result of the military conflict in Ukraine. Any one of these occurrences would adversely impact our supply chain.

Because of our dependence on our suppliers, changes in our relationships with any of them can result in disruptions to the supply chain, which can materially impact our business. For instance, we may be unable to quickly establish or qualify replacement suppliers creating production interruptions, delays and inefficiencies. Finding substitute manufacturers may be expensive, time-consuming or impossible and could result in a significant interruption in the supply of one or more products causing us to lose revenues and suffer damage to our customer relationships. Technology changes by our service providers, vendors, and other third parties could disrupt access to required manufacturing capacity or require expensive, time-consuming development efforts to adapt and integrate new equipment or processes. In the event of technology changes, delivery delays, labor stoppages or shortages, or shortages of, or increases in price for these items, sales may decrease and our business and prospects may be harmed.

We use distributors for a portion of the importation, marketing and sales efforts related to our products and services, which exposes us to risks to our sales and operations, including the risk that these distributors do not comply with applicable laws or our internal procedures.

In addition to our direct sales force, we have and expect to continue to use distributors to import, market, sell, service and support our products. Our agreements with these distributors are generally non-exclusive and terminable by either party with little notice. If alternative distributors must be quickly found and trained in the use, marketing, sales and support of our products and services, our revenues and ability to sell or service our products in markets key to our business could be adversely affected. These distributors may also choose to sell alternative or competing products or services. In addition, we may be held responsible for the actions of these distributors and their employees and agents for compliance with laws and regulations, including fair competition, bribery and corruption, trade compliance, safety, data privacy and marketing and sales activities. A distributor may also affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if it holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for non-compliance or prevents us from taking control of any such authorization. It may be difficult, expensive, and time-consuming for us to re-establish market access or regulatory compliance.

A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could disrupt our supply chain and impact our revenues or gross margin.

We are dependent on commercial freight carriers, primarily UPS, to deliver our products. If the operations of carriers are disrupted, we may be unable to timely deliver our products to our customers who may choose alternative products which could cause our net revenues and gross margin to materially decline. For example, after Russia's military attacks in Ukraine in 2022, UPS ceased shipments to Russia and we suspended new product sales there. Moreover, when fuel costs increase, our freight costs generally do so as well. In 2022, due to increased fuel costs, we experienced a material increase in freight costs. In addition, we earn an increasingly larger portion of our total revenues from international sales, which carry higher shipping costs that could negatively impact our gross margin and results of operations. If freight costs materially increase and we are unable to successfully pass all or significant portions of the increases along to our customers, or we cannot otherwise offset such increases in our cost of net revenues, our gross margin and financial results could be materially affected.

Our success depends largely on the talents and efforts of our personnel, and if we are unable to attract, motivate, train or retain our personnel, it may be more difficult to grow effectively and pursue our strategic priorities, and could materially effect on our results of operations.

We are highly dependent on the talent and effort of our personnel, including highly skilled personnel like orthodontists and production technicians in our treatment planning facilities, and employees on our clinical engineering, technology development and sales teams. As a result, we strive to retain our personnel, by providing competitive compensation and benefits, development opportunities and training, flexible work options, and an inclusive corporate culture. However, there is substantial competition in our industry for highly-skilled personnel, in particular significantly higher demand for technical and digital talent. Furthermore, our compensation and benefit arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating existing employees. In addition, other internal and external factors can impact our ability to hire and retain talent, including insufficient advancement or career opportunities and restrictive immigration policies. The loss of any of our key personnel, particularly executive management, key research and development personnel or key sales team personnel, could harm our business and prospects and could impede the achievement of our research and development, operational or strategic objectives.

We provide significant training to our personnel and our business will be impacted if our training fails to properly prepare our personnel to perform the work required, we are unable to successfully instill technical expertise in new and existing personnel or if our techniques prove unsuccessful or not cost-effective. Moreover, for certain roles, this training and experience can make key personnel, such as our sales personnel, highly desirable to competitors and lead to increased attrition. The loss of the services and knowledge from our highly-skilled employees may significantly delay or prevent the achievement of our development and business objectives and could harm our business. For example, it can take up to twelve months or more to train sales representatives to successfully market and sell our products and for them to establish strong customer relationships.

Additionally, facilitating seamless leadership transitions for key positions is a critical factor in sustaining the culture and maintaining the success of our organization. If our succession planning efforts are not effective, it could adversely impact our business. We continue to assess the key personnel that we believe are essential to our long-term success, as future organizational changes could also cause our employee attrition rate to increase. If we fail to effectively manage any organizational or strategic changes, our financial condition, results of operations, and reputation, as well as our ability to successfully attract, motivate and retain key employees, could be harmed.

In 2022, we gradually reopened many of our offices that had been substantially closed to employees during the COVID-19 pandemic. Where our offices have reopened, we have adopted a hybrid work schedule that allows many of our employees the opportunity to collaborate and connect with others in our offices for some days of the week while having the

option to work remotely other days. This hybrid work approach that we have adopted may materially increase our costs or create unforeseen challenges or complications, including:

- difficulties maintaining our corporate culture, disruption of morale or decreased loyalty;
- difficulties with hiring and retention, particularly if we must compete against other companies that offer generous or broad remote working policies;
- negative impacts to collaboration, performance and productivity;
- increased stress, fatigue or "burn out" by employees unable to disengage their work life from home life;
- increased operational, governance, compliance, and tax risks;
- increased attrition or limits to our ability to attract employees who prefer to continue working remotely full time, or in offices or geographies different from where they were hired or are expected to work;
- problems managing office space requirements;
- concerns regarding favoritism or discrimination;
- strains to our business continuity plans and difficulties achieving our strategic objectives; and
- increased labor and employment claims and litigation.

Also, we believe a key factor in our success has been the culture we have created that emphasizes a shared vision and values focusing on agility, customer success and accountability. We believe this culture fosters an environment of integrity, innovation, creativity, and teamwork. We have experienced and may continue to experience in the future, difficulties attracting and retaining employees that meet the qualifications, experience, compliance mindset and values we expect. If we are unable to attract and retain personnel that meet our selection criteria or relax our standards in order to meet the demands of our growth or if our growth is not managed effectively, our corporate culture, ability to achieve our strategic objectives, and our compliance with obligations under our internal controls and other requirements may be harmed. This could have a material adverse effect on our results of operations and our ability to maintain market share.

We are dependent on our marketing activities to deepen our market penetration and raise awareness of our brand and products, which may not prove successful or may become less effective or more costly to maintain in the long term.

Our marketing efforts and costs are significant and include national and regional campaigns in multiple countries involving television, print and social media and, more recently, alliances with professional sports teams, social media influencers and other strategic partners. We attempt to structure our advertising campaigns to increase brand awareness, adoption and goodwill; however, there is no assurance our campaigns will achieve the returns on advertising spend desired, increase brand or product awareness sufficiently or generate goodwill and positive reputational goals. Moreover, should any entity or individual endorsing us or our products take actions, make or publish statements in support of, or lend support to events or causes which may be perceived by a portion of society negatively, our sponsorships or support of these entities or individuals may be questioned, boycotts of our products announced, and our reputation may be harmed, any of which could have a material effect on our gross margin and business overall.

In addition, various countries prohibit certain types of marketing activities. For example, some countries restrict direct to consumer advertising of medical devices. We could run afoul of restrictions and be ordered to stop certain marketing activities. Moreover, competitors do not always follow these restrictions, creating an unfair advantage and making it more difficult and costly for us to compete.

Additionally, we rely heavily on data generated from our campaigns to target specific audiences and evaluate their effectiveness, particularly data generated from internet activities on mobile devices. To obtain this data, we are dependent on third parties and popular mobile operating systems, networks, technologies, products, and standards that we do not control, such as the Android and iOS operating systems and mobile browsers. Any changes in such systems that degrade, reduce or eliminate our ability to target or measure the results of ads or increase costs to target audiences could adversely affect the effectiveness of our campaigns. For example, Apple has released mobile operating systems that include significant data privacy changes that may limit our ability to interpret, target and measure ads effectively.

Legal, Regulatory and Compliance Risks

We are subject to antitrust and competition regulatory activity, litigation and enforcement actions that may result in fines, penalties, restrictions on our business practices, and product or operational changes which could materially impact our business.

We are and may be in the future subject to antitrust or competition related investigations, enforcement actions, and settlements, by governmental agencies, competitors, consumers, customers, and others which could cause us to incur substantial costs or require us to change our business practices in a manner materially adverse to our business. Governments, enforcement

authorities and other legislative bodies are actively developing new competition laws and regulations aimed at the technology sector, artificial intelligence and digital platforms, coordinating globally, and enforcing competition laws and regulations, and this includes scrutiny in potentially large markets such as the EU, U.S., and China. Government regulatory actions and court decisions may result in fines or hinder our ability to provide certain benefits to our consumers, reducing the attractiveness of our products and the revenue that comes from them. Other companies and government agencies have in the past and may in the future allege that our actions violate the antitrust or competition laws or otherwise constitute unfair competition. Such claims and investigations, even if without foundation, may be very expensive to defend, involve negative publicity and substantial diversion of management time and effort and could result in significant judgments against us or require us to change our business practices, any of which may materially impact our results of operations.

Obtaining approvals and complying with governmental regulations, particularly those related to personal healthcare information, financial information, quality systems, anti-corruption and anti-bribery are expensive and time-consuming. Any failure to obtain or maintain approvals or comply with regulations regarding our products or services or the products and services of our suppliers or customers could materially harm our sales, result in substantial penalties and fines and cause harm to our reputation.

We and many of our healthcare provider customers, suppliers and distributors are subject to extensive and frequently changing regulations under numerous federal, state, local and foreign laws, including those regulating:

- the storage, transmission and disclosure of medical information and healthcare records;
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; and
- the design, manufacture marketing and advertising of our products.

The healthcare and technology markets are also highly regulated and subject to changing political, economic and regulatory influences. Global regulators are expanding and changing the regulations and guidance for products, which can limit the potential benefits of products and result in protracted review timelines for new product introductions. We are also incorporating artificial intelligence into our software to make it more effective for us, our customers, suppliers and consumers; however, this subjects us to risks of compliance with the expanding and changing regulations regarding the use artificial intelligence. Our critical vendors and service providers are similarly subject to various regulations. Our failure or the failure of our suppliers, customers, advertisers and influencers to strictly adhere to clearances or approvals in the labeling, marketing and sales of our products and services could subject us to claims or litigation, including actions alleging false or misleading advertising or other violations of laws or regulations, which may result in costly investigations, fines, penalties, as well as material judgments, settlements or decrees. We are also subject to complex and changing environmental and health and safety regulations. Additionally, a large portion of our revenues are derived from international sales and we are dependent on our international operations, which exposes us to additional foreign regulations not otherwise described herein, including without limitation, pricing regulations imposed by governments like the volume-based procurement regulations in China. There can be no assurance that we will adequately address the business risks associated with the implementation and compliance with such laws and our internal processes and procedures to comply with such laws or that we will be able to take advantage of any resulting business opportunities.

Furthermore, in general before we can sell a new medical device or market a new use of or claim for an existing product, we must obtain clearance or approval before marketing the product unless an exemption applies. For instance, in the U.S., FDA regulations are wide ranging and govern, among other things, product design, development, manufacturing and testing; product labeling and product storage. It takes significant time, effort and expense to obtain and maintain clearances or approvals of products and services from governmental regulators such as the FDA, and there is no guarantee we will successfully or timely obtain or maintain approvals in all or any of the countries in which we do business. In other countries, the requirements, time, effort and expense to obtain and maintain similar marketing authorizations may differ materially from those of the FDA. Moreover, these laws may change, resulting in additional time and expense or loss of market access. If approvals to market our products or services are delayed, we may be unable to offer them in markets we deem important to our business. Additionally, failure to comply with applicable regulatory requirements could result in enforcement actions with sanctions including, among other things, fines, civil penalties and criminal prosecution. Failure or delays to obtain or maintain regulatory approvals or to comply with regulatory requirements may materially harm our domestic or international operations, and adversely impact our business.

We and certain of our vendors must also comply with facility registration and product listing requirements of regulators and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Failure to satisfactorily correct an adverse inspection finding or to comply with applicable manufacturing regulations can result in enforcement actions, we may be required to find alternative manufacturers, which could be a long and costly process and may cause reputational harm. Enforcement actions by regulators could have a material effect on our business.

We are also subject to anti-corruption and anti-bribery ("ABAC") laws such as the Foreign Corrupt Practices Act ("FCPA") and the U.K. Bribery Act of 2010, which generally prohibit corrupt payments to foreign officials for the purpose of obtaining or keeping business, securing an advantage and directing business to another. To comply with ABAC laws, regulators require the maintenance of accurate books and records and a system of internal accounting controls. Under the FCPA, we may be held liable for any corrupt actions taken by directors, officers, employees, agents, or other strategic or local partners or representatives.

In addition, while we have policies requiring our personnel to comply with applicable laws and regulations and we provide significant training to foster compliance, they may not properly adhere to our policies or applicable laws or regulations, including such as our policies on the use of certain electronic communications and maintaining accurate books and records. If our personnel or the personnel of our agents or suppliers fail to comply with any laws, regulations, policies or procedures, or we fail to audit and enforce compliance, it could subject us to harm to our reputation, loss of customers, loss or revenues, or regulatory investigations, actions and fines.

Security breaches, data breaches, cyber attacks, other cybersecurity incidents or the failure to comply with privacy, security and data protection laws could materially impact our operations, patient care could suffer, we could be liable for damages, and our business, operations and reputation could be harmed.

We retain confidential customer personal and financial, patient health information and our own proprietary information and data essential to our business operations. We rely upon the effective operation of our IT systems, and those of our service providers, vendors, and other third parties to safeguard the information and data. Additionally, our success may be dependent on the success of healthcare providers, many of whom are comprised of individual or small operations with limited IT experience and inadequate or untested security protocols, in managing data privacy and data security requirements. It is critical that the facilities, infrastructure and IT systems on which we depend to run our business and the products we develop remain secure and be perceived by the marketplace and our customers to be secure. Despite the implementation of security features in our products and security measures in our IT systems, we and our service providers, vendors, and other third parties continue to be targeted by or subject to physical break-ins, computer viruses or other malicious code, unauthorized or fraudulent access, programming errors or other technical malfunctions, hacking or phishing attacks, malware, ransomware, employee error or malfeasance, cyber attacks, and other breaches of IT systems or similar disruptive actions, including by organized groups and nation-state actors. For example, we have experienced, and may again experience in the future, cybersecurity incidents and unauthorized internal employee exfiltration of company information.

Further, the frequency of third-party cyber-attacks has increased over the last several years. The military conflict in Ukraine may cause nation-state actors or hackers sympathetic to either side of the conflict to carry out cyber-attacks to achieve their goals, which may include espionage, information gathering operations, monetary gain, ransomware, disruption, and destruction. To respond to potential increases in cyber-attacks, in 2022, we increased efforts to identify and respond to any attacks, including placing our cybersecurity operations team on high alert. Significant service disruptions, breaches in our infrastructure and IT systems or other cybersecurity incidents could expose us to litigation or regulatory investigations, impair our reputation and competitive position, be distracting to our management, and require significant time and resources to address. Affected parties or regulatory agencies could initiate legal or regulatory action against us, which could prevent us from resolving the issues quickly or force us to resolve them in unanticipated ways, cause us to incur significant expense and liability, or result in judicial or governmental orders forcing us to cease operations or modify our business practices in ways that could materially limit or restrict the products and services we provide. Concerns over our privacy practices could adversely affect others' perception of us and deter customers, patients and partners from using our products. In addition, patient care could suffer, and we could be liable if our products or IT systems fail to deliver accurate and complete information in a timely manner. We have internal monitoring and detection systems as well as cybersecurity and other forms of insurance coverage related to a breach event covering expenses for notification, credit monitoring, investigation, crisis management, public relations and legal advice. However, damages and claims arising from such incidents may not be covered or may exceed the amount of any coverage and do not cover the time and effort we may incur investigating and responding to any incidents, which may be material. The costs to eliminate, mitigate or recover from security problems and cyber attacks and incidents could be material and depending on the nature and extent of the problem and the networks or products impacted, may result in network or systems interruptions, decreased product sales, or data loss that may have a material impact on our operations, net revenues and operating results.

Additionally, our globally-dispersed installed base of iTero intraoral scanners at customer, strategic business partner or other locations may be independently or collectively the target of a cybersecurity incident or attack or subject to the intrusion of a virus, bug, or other similar negative intruder. Due to the large and growing number of these decentralized locations, we may not be able to, or not have the capacity, knowledge, or infrastructure to, respond to or remedy a cybersecurity issue in a timely manner, which may cause loss or damage to us or our customers or strategic business partners or may cause further malfunctions in, or damage to, our servers, databases, systems or products and services, loss or damage of our data, interruption or temporary cessation of our operations, or an overall negative impact to our business or reputation.

We are also subject to federal, state and foreign laws and regulations, including regulations affecting the security and privacy of patient healthcare information applicable to healthcare providers and their business associates, such as HIPAA, ones relating to privacy, data security and protection, content regulation, and consumer protection, among others. We are subject to various national and regional data localization or data residency laws such as the General Data Protection Regulation in the EU and analogous laws in China which generally require that certain types of data collected within a country be stored and processed only within that country or approved countries and other countries are considering enacting similar data localization or data residency laws. We have and likely will again in the future be required to implement new or expand existing data storage protocols, build new storage facilities, and/or devote additional resources to comply with such laws, any of which could be costly. We are also subject to data export restrictions and international transfer laws which prohibit or impose conditions upon the transfer of such data from one country to another. These laws and regulations are constantly evolving and may be interpreted, applied, created or amended in a manner that could adversely affect our business.

Our business exposes us to potential liability for the quality and safety of our products and services, how we advertise and market those products and services and how and to whom we sell them, and we may incur substantial expenses or be found liable for substantial damages or penalties if we are subject to claims or litigation.

Our products and services involve an inherent risk of claims concerning their design, manufacture, safety and performance, how they are marketed and advertised in a complex framework of highly regulated domestic and international laws and regulations, how we package, bundle or sell them to customers who may be private individuals or companies or public entities such as hospitals and clinics and how we train and support doctors, their staffs and patients who administer or use our products. Moreover, consumer products and services are routinely subject to claims of false, deceptive or misleading advertising, consumer fraud and unfair business practices. Additionally, we may be held liable if any product we develop or manufacture or services we offer or perform causes injury or is otherwise found unhealthy. If our products are safe but they are promoted for use or used in unintended or unexpected ways or for which we have not obtained clearance or approvals ("off-label" usage), we may be investigated, fined or have our products or services enjoined or approvals rescinded or we may be required to defend ourselves in litigation. Although we maintain insurance for product liability, business practices and other types of activities we make or offer, coverage may not be available on acceptable terms, if at all, and may be insufficient for actual liabilities. Any claim for product liability, sales, advertising and business practices, regardless of its merit or eventual outcome, could result in material legal defense costs and damage our reputation, increase our expenses and divert management's attention.

Increased focus on current and anticipated environmental, social and governance ("ESG") laws and increased scrutiny of our ESG policies and practices may materially increase our costs, expose us to potential liability, adversely impact our reputation, employee retention, willingness of customers and suppliers to do business with us and willingness of investors to invest in us.

Our operations are subject to a variety of existing local, regional and global ESG laws and regulations, and we will likely be required to comply with new, broader, more complex and more costly laws and regulations that focus on ESG matters. Our compliance obligations will likely span all aspects of our business and operations, including product design and development, materials sourcing and other procurement activities, product packaging, product safety, energy and natural resources usage, facilities design and utilization, recycling and collection, transportation, disposal activities and workers' rights.

Environmental regulations related to greenhouse gases are expected to have an increasingly larger impact on our or our suppliers' energy sources. Many U.S. and foreign regulators have enacted or are considering enacting new or additional disclosure requirements or limits on the emissions of greenhouse gases, including, but not limited to, carbon dioxide and methane, from power generation units using fossil fuels. The effects of greenhouse gas emission limits on power generation are subject to significant uncertainties, including the timing of any new requirements, levels of emissions reductions and the scope and types of emissions regulated. These limits may have the effect of increasing our costs and those of our suppliers and could result in manufacturing, transportation and supply chain disruptions and delays if clean energy alternatives are not readily available in adequate amounts when required. Moreover, alternative energy sources, coupled with reduced investments in traditional energy sources and infrastructure, may fail to provide the predictable, reliable, and consistent energy that we, our suppliers and other businesses need for operations.

Regulations related to sourcing of certain metals may have an impact on our business. For instance, the sourcing and availability of metals that may be used in the manufacture of, or contained in, our products may be affected by laws and regulations regarding the use of minerals obtained from certain regions of the world like the Democratic Republic of Congo and adjoining countries. Although we do not believe that we or our suppliers source minerals from this region, these laws and regulations may decrease the number of suppliers capable of supplying our needs for certain metals, thereby negatively affecting our ability to manufacture products in sufficient quantities or at competitive prices, leading customers to potentially choose competitive goods and services.

Meeting our obligations under existing ESG laws, rules, or regulations is already costly to us and our suppliers, and we expect those costs to increase as new laws are enacted, possibly materially. Additionally, we expect regulators to perform investigations, inspections and periodically audit our compliance with these laws and regulations, and we cannot provide assurance that our efforts or operations will be compliant. If we fail to comply with any requirements, we could be subject to significant penalties or liabilities and we may be required to implement new and materially more costly processes and procedures to come into compliance. Further these laws are subject to unpredictable changes. Even if we successfully comply with these laws and regulations, our suppliers may fail to comply. We may also suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are conflict free. In all of these situations, customers may stop purchasing products from us, and may take legal action against us, which could harm our reputation, revenues and results of operations.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and customers are also increasingly focused on corporate ESG practices. Additionally, public interest and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet investor or other industry stakeholders' evolving expectations and standards, including environmental stewardship, support for local communities, board of director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted, customers and suppliers may be unwilling to do business with us and investors may be unwilling to invest in us. In addition, as we work to align our ESG practices with industry standards, we have expanded and will likely continue to expand our disclosures in these areas. We also expect to incur additional costs and require additional resources to monitor, report, and comply with our various ESG practices. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, report on our ESG efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our reputation, business, financial performance, growth, and stock price may be adversely impacted.

Intellectual Property Risks

Our success depends in part on our proprietary technology, and if we fail to successfully obtain or enforce our intellectual property ("IP") rights, our competitive position may be harmed.

Our success depends in part on our ability to maintain existing IP rights and obtain and maintain further IP protection for our products. Our inability to do so could harm our competitive position.

We rely on our portfolio of issued and pending patent applications in the U.S. and other countries to protect a large part of our IP and our competitive position; however, these patents may be insufficient to protect our IP rights because our patents may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products and foreign patents protections may be more limited than those provided under U.S. patents and IP laws. Additionally, international IP rights laws are typically less protective than the protections afforded under the laws of the U.S.

Additionally, we may fail to timely file a patent application, or any of our patent applications may not result in an issued patent or the scope of the patent ultimately issued may be narrower than we initially sought. We may not be afforded the protection of a patent if our currently pending or future patent filings do not result in the issuance of patents or we fail to apply for patent protection. We may fail to apply for a patent if our personnel fail to disclose or recognize new patentable ideas or innovations. Remote working can decrease the opportunities for our personnel to collaborate, thereby reducing the opportunities for effective invention disclosures and patent application filings. We may choose not to file a foreign patent application if the limited protections provided by a foreign patent do not outweigh the costs to obtain it.

We also protect our IP through copyrights, trademarks, trade secrets, and confidentiality obligations. We generally enter into confidentiality agreements with our employees, consultants and collaborative partners upon commencement of a relationship with us. However, despite the existence of these protections, we have experienced incidents in which our proprietary information has been misappropriated and believe it could be misappropriated again in the future. If these agreements do not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, adequate remedies may not exist to prevent unauthorized uses or disclosures.

Our inability to maintain the proprietary nature of our technology through patents, copyrights or trade secrets would impair our competitive advantages and could have a material effect on our operating results, financial condition and future growth prospects. In particular, a failure to protect our IP rights might allow competitors to copy our technology or create counterfeit or pirated versions of our products, which could adversely affect our reputation, pricing and market share.

Litigation regarding our IP rights, rights claimed by third parties, or IP litigation by any vendors on whose products or services we rely for our products and services may impact our ability to grow our business, adversely impact our results of operations and adversely impact our reputation.

Extensive litigation over patents and other IP rights is common in medical device, optical scanner, 3D printing and other technologies and industries on which our products and services are based. Litigation, interferences, oppositions, re-exams, *inter partes* reviews, post grant reviews or other proceedings have been necessary and will likely be needed in the future to determine the validity and scope of certain of our IP rights and the IP rights claimed by third parties. These proceedings are used to determine the validity, scope or non-infringement of certain patent rights pertinent to the manufacture, use or sale of our products and the products of competitors. We have been sued for infringement of third parties' patents in the past and we are currently defending patent infringement lawsuits and other legal claims. In addition, we periodically receive letters from third parties drawing our attention to their IP rights and there may be other third-party IP rights of which we are presently unaware. Asserting or defending these types of proceedings can be unpredictable, protracted, time-consuming, expensive and distracting to management and technical personnel. Their outcomes could adversely affect the validity and scope of our patent or other IP rights, hinder our ability to manufacture and market our products, require us to seek a license for infringing products or technologies or result in the assessment of significant monetary damages. An unfavorable ruling could include monetary damages, an injunction prohibiting us from selling our products, or an exclusion order preventing us from importing our products in one or more countries. Moreover, independent actions by competitors, customers or others have been brought alleging that our efforts to enforce our patent or other IP rights constitute unfair competition or violations of antitrust laws in the U.S. and other jurisdictions and investigations and additional litigation based on the same or similar claims may be brought in the future. The potential effects on our business operations resulting from litigation, whether or not ultimately determined in our favor or settled by us, are costly and could materially affect our results of operations and reputation.

Financial, Tax and Accounting Risks

If our goodwill or long-lived assets become impaired, we may be required to record a material charge to earnings.

Under U.S. Generally Accepted Accounting Practices ("GAAP"), we review our goodwill and long-lived asset group for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. Additionally, goodwill must be tested for impairment at least annually. The qualitative and quantitative analysis used to test goodwill are dependent upon various assumptions and reflect management's best estimates. Changes in certain assumptions, including revenue growth rates, discount rates, earnings multiples and future cash flows may cause a change in circumstances indicating that the carrying value of goodwill or the asset group may be impaired and assessing these assumptions and predicting and forecasting future events can be difficult. Goodwill and purchased assets require periodic fair value assessments to determine if they have become impaired. Consequently, we may be required to record a material charge to earnings in the financial statements during the period in which any impairment of goodwill or long-lived asset group is determined.

Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.

We prepare our consolidated financial statements in conformity with GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or in the way these policies are interpreted by us or regulators could have a material effect on our reported results and may even retroactively affect previously reported financial statements.

We are required to annually assess our internal control over financial reporting and any adverse results from such assessment may result in a loss of investor confidence in our financial reports and adversely effect our stock price.

We are required to furnish in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting that includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether our internal control over financial reporting is effective. Our internal controls may become inadequate because of changes in personnel, updates and upgrades to existing software, failure to maintain accurate books and records, changes in accounting standards or interpretations of existing standards, and, as a result, the degree of compliance of our internal control over financial reporting with the existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and increases our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), the timely filing of our financial reports could be delayed or we could be required to restate past reports, and cause us to lose investor confidence in the accuracy and completeness of our financial reports in the future, which could have an adverse effect on our stock price.

If we fail to manage our exposure to global financial and securities market risks successfully, our operating results and financial statements could be materially impacted.

A majority of our marketable investments are investment grade, liquid, fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment

portfolio correlates with the credit condition of the U.S. financial sector. In an unstable credit or economic environment, it is necessary to assess the value of our investments more frequently and we might incur material realized, unrealized or impairment losses associated with these investments.

Our effective tax rate may vary significantly from period to period.

Align operates globally and is subject to taxes in the U.S. and foreign countries. Various internal and external factors may affect our future effective tax rate. These factors include changes in the global economic environment, changes in our legal entity structure or activities performed within our entities, changes in our business operations, changes in tax laws, regulations and/or rates, new or changes to accounting pronouncements, changing interpretations of existing tax laws or regulations, changes in relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, changes in overall levels of pretax earnings, the future levels of tax benefits of stock-based compensation, settlement of income tax audits and non-deductible goodwill impairments.

Our effective tax rate is also dependent in part on forecasts of full year results which can vary materially. Furthermore, we may continue to experience significant variation in our effective tax rate related to excess tax benefits on stock-based compensation, particularly in the first quarter of each year when the majority of our equity awards vest.

New tax laws and practices, changes to existing tax laws and practices, or disputes regarding the positions we take regarding tax laws, could negatively affect our provision for income taxes as well as our ongoing operations.

We are subject to tax laws both within and outside of the U.S. requiring significant judgment in determining our worldwide provision for income taxes. Changes in tax laws or changes to how those laws are applied to our business in practice, could affect the amount of tax to which we are subject and the manner in which we operate. Additionally, the Organization for Economic Cooperation and Development's ("OECD") Base Erosion and Profit Shifting ("BEPS") project has resulted in considerable new reporting obligations worldwide as OECD member countries have implemented its guidance. The OECD continues to publish guidance pursuant to the BEPS and other projects which, if adopted by member countries, may affect our tax positions in many of the countries in which we do business.

Moreover, the application of indirect taxes (such as sales and use tax ("SUT"), value-added tax ("VAT"), goods and services tax ("GST"), and other indirect taxes) to our operations is complex and evolving. U.S. states, local and foreign taxing jurisdictions have differing rules and regulations governing differing types of taxes, and these rules and regulations are subject to varying interpretations and exemptions that may change over time. We collect and remit SUT, VAT, GST and other taxes in many jurisdictions and we are routinely subject to audits. We are also routinely subject to audits regarding our tax reporting and remissions by local and national government, and we may also be subject to audits in U.S. states, local and foreign jurisdictions for which we have not accrued tax liabilities. The positions we take regarding taxes as well as the amounts we collect or remit may be challenged and we may be liable for failing to collect or remit all or any portion of taxes deemed owed or the taxes could exceed our estimates. One or more U.S. states or countries may seek to impose incremental or new sales, use, or other tax collection obligations on us or may determine that such taxes should have but have not been paid by us. If we dispute rulings or positions taken by tax authorities, we may incur expenses and expend significant time and effort to defend our positions, which may be costly.

On August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was enacted. It contains numerous new U.S. federal tax law provisions, including a corporate alternative minimum tax on adjusted financial statement income and an excise tax on corporate stock repurchases, both effective after December 31, 2022. We continue to evaluate the IRA's impact to our business, which may be material.

The application of existing, new, or future tax laws, and results of audits, whether in the U.S. or internationally, could harm our business. Furthermore, there have been and will continue to be substantial ongoing costs associated with complying with the various tax requirements and defending our positions in the numerous markets in which we conduct or will conduct business.

Historically, the market price for our common stock has been volatile.

The market price of our common stock is subject to rapid and large price fluctuations attributable to various factors, many of which are beyond our control. The factors include:

- quarterly variations in our results of operations and liquidity or changes in our forecasts and guidance;
- our ability to regain or sustain our historical growth rates;
- changes in recommendations by the investment community or speculation in the press or investment community regarding estimates of our net revenues, operating results or other performance indicators;
- announcements by us or our competitors or new market entrants, including strategic actions, management changes, and material transactions or acquisitions;

- technical factors in the public trading markets for our stock that may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as it may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock, fractional share trading, and other technical trading factors or strategies;
- announcements regarding stock repurchases, sales or purchases of our common stock by us, our officers or directors, credit agreements and debt issuances;
- announcements of technological innovations, new, additional or revised programs, business models, products or product offerings by us, our customers or competitors;
- key decisions in pending litigation, new litigation, settlements, judgments or decrees; and
- general economic market conditions, including rising interest rates, inflationary pressures, recessions, consumer sentiment and demand, global political conflict and industry factors unrelated to our actual performance.

In addition, the stock market in general, and the market for technology and medical device companies, in particular, have experienced extreme price and volume fluctuations often unrelated to or disproportionate to corporate operating performance. These broad market and industry factors may include market expectations of, or actual changes in, monetary policies that have the goal of easing or tightening interest rates such as the U.S. federal funds rate and austerity measures of governments intended to control budget deficits. Historically, securities litigation, including securities class action lawsuits and securities derivative lawsuits, is often brought against an issuer following periods of volatility in the market price of its securities and we have not been exempt from such litigation.

We cannot guarantee that we will continue to repurchase our common stock in the future, and any repurchases that we may make may not achieve our desired objectives.

We have a history of recurring stock repurchase programs intended to return capital to our investors. Future stock repurchase programs are contingent on a variety of factors, including our financial condition, results of operations, business requirements, and our Board of Directors' continuing determination that stock repurchases are in the best interests of our stockholders and in compliance with all applicable laws and agreements. There is no assurance that we will continue repurchasing our common stock in the future, consistent with historical levels or at all, or that our stock repurchase programs will have a beneficial impact on our stock price. Additionally, the IRA, among other things, imposes a 1% excise tax on any domestic corporation that repurchases its stock after December 31, 2022, which will increase our cost to make repurchases and may impact if and how much stock we choose to repurchase in the future.

Future sales of significant amounts of our common stock may depress our stock price.

A significant percentage of our outstanding common stock is currently owned by a small number of stockholders. These stockholders have sold in the past, and may sell in the future, large amounts of our stock over relatively short periods of time. Sales of substantial amounts of our stock by existing stockholders may adversely affect the market price of our stock by creating the perception of difficulties or problems with our business that may depress our stock price.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We occupy several leased and owned facilities. As of December 31, 2022, the significant facilities occupied were as follows:

Location	Lease/Own	Primary Use
Tempe, Arizona, U.S.A.	Lease	Office for corporate headquarters
San Jose, California, U.S.A.	Own	Office for research & development and administrative personnel
Raleigh, North Carolina, U.S.A.	Own	Office for Americas regional headquarters
San Jose, Costa Rica	Lease and Own	Office for administrative personnel, treatment personnel, and customer care
Wroclaw, Poland	Lease and Own	Manufacturing and office for treatment and administrative personnel
Petah Tikva, Israel	Lease and Own	Manufacturing and office for research & development and administrative personnel
Rotkreuz, Switzerland	Lease	Office for EMEA regional headquarters
Juarez, Mexico	Own	Manufacturing and office for administrative personnel
Ziyang, China	Own	Manufacturing and office for administrative personnel

We believe our existing facilities are in good operating condition and are suitable for the conduct of our business. The facilities noted above are used mostly by all our reportable segments.

Item 3. Legal Proceedings.

For a discussion of legal proceedings, refer to *Note 7 "Legal Proceedings" of the Notes to Consolidated Financial Statements* in Part II, Item 8 of this Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

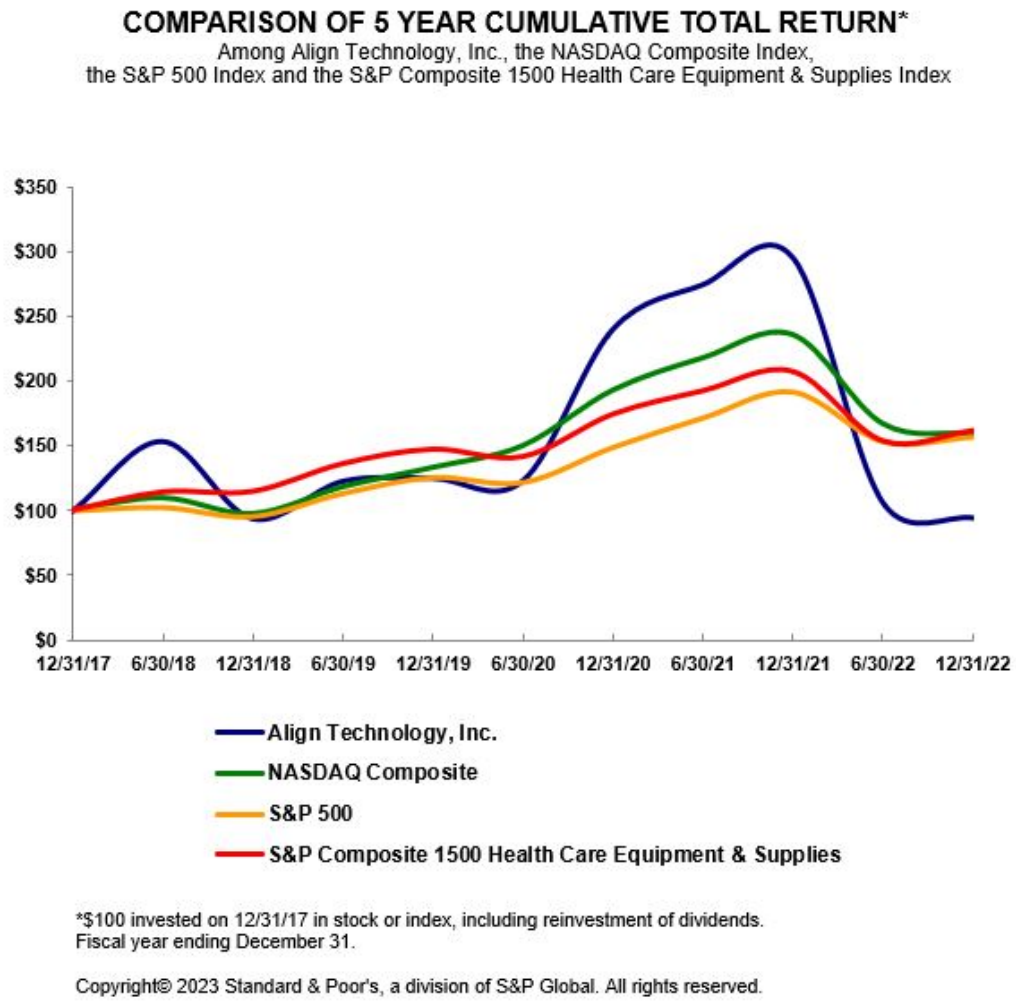
Market Information

Our common stock is traded on the NASDAQ Global Market under the symbol ALGN. As of February 20, 2023, there were approximately 53 holders of record of our common stock. Because the majority of our shares of outstanding common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Performance Graph

Notwithstanding any statement to the contrary in any of our previous or future filings with the SEC, the following information relating to the price performance of our common stock shall not be deemed "filed" with the SEC or "Soliciting Material" under the Securities Exchange Act of 1934, as amended, or subject to Regulation 14A or 14C, or to liabilities of Section 18 of the Exchange Act except to the extent we specifically request that such information be treated as soliciting material or to the extent we specifically incorporate this information by reference.

The graph below matches our cumulative 5-year total stockholder return on common stock with the cumulative total returns of the NASDAQ Composite index, the S&P 500 index and the S&P 1500 Composite Health Care Equipment & Supplies index. The graph tracks the performance of a $100 investment in our common stock and each index (with the reinvestment of all dividends) from December 31, 2017 to December 31, 2022.



Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table summarizes the stock repurchase activity for the three months ended December 31, 2022:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs[1]
October 1, 2022 through October 31, 2022	848,266	$ 188.62	848,266	$ 249,926,094
November 1, 2022 through November 30, 2022	—	$ —	—	$ 249,926,094
December 1, 2022 through December 31, 2022	—	$ —	—	$ 249,926,094
Total	848,266		848,266	

[1] *May 2021 Repurchase Program.* On May 13, 2021, we announced that our Board of Directors had authorized a plan to repurchase up to $1.0 billion of our common stock. See *Note 10* "*Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements* for details on the May 2021 Repurchase Program.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

A discussion regarding our financial condition and results of operations for fiscal 2022 compared to fiscal 2021 is presented under Results of Operations of this Form 10-K. Discussions regarding our financial condition and results of operations for fiscal 2021 compared to 2020 have been omitted from this Annual Report on Form 10-K, but can be found in *"Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations"* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 25, 2022, which is available without charge on the SEC's website at *www.sec.gov* and on our investor relations website at *investor.aligntech.com*.

Executive Overview of Results

Trends and Uncertainties

Our business strategic priorities remain focused on four principal pillars for growth: (i) international expansion; (ii) GP adoption; (iii) patient demand and conversion; and (iv) orthodontic utilization. Our growth strategy depends on our ability to facilitate the digital transformation of dentistry happening around the world, our continuous focus on innovation, and expansion to meet and exceed evolving customer expectations as the array of products and services available to them increases.

We strive to deliver on each of our strategic growth drivers through a variety of interrelated enterprise-wide efforts including:

- Continuing penetration and adoption of Invisalign products, intraoral scanners and CAD/CAM solutions in international markets by investing in manufacturing operations, research and development, clinical treatment planning, sales and marketing and building our quality and regulatory capabilities in existing and emerging markets globally. For instance, in 2022, we opened a new aligner fabrication facility in Wroclaw, Poland as a part of our strategy to bring operational facilities closer to customers to serve them more quickly and respond to their needs more effectively as well as new treatment planning operations in targeted regional geographies. We also diversified our research and development activities throughout Europe in 2022, which has created a longer term, more stable environment for consistent hiring, retention and innovation in a variety of high technology sectors.

- Targeting growth opportunities with international orthodontists and GP customers, particularly with adopters of digital dentistry platforms by tailoring our sales and marketing strategies, manufacturing operations and resources around the

unique needs of each customer channel. As we continue growing, we intend to opportunistically expand our research, development, manufacturing, treatment planning, and sales and marketing operations to meet local and regional demand thoughtfully and deliberately. Over the longer-term, we expect international revenues to grow faster than Americas' revenues as a result of growing international demand, our continued investment in international market expansion, the size of the market opportunities and our relatively low market penetration in these regions.

- Building confidence within the GP and orthodontic communities through training and education efforts to increase their adoption and utilization of digital dental practice transformation and clear aligner treatment. Accordingly, we continue to expand our Invisalign customer base by educating new doctors on the benefits of digital dentistry through the Invisalign system and demonstrating to GPs and orthodontists how the iTero portfolio of intraoral scanners and CAD/CAM restorative services and workflows can increase revenues and profitability for their dental practices by enhancing patient experiences and creating operation practice efficiencies.

- Investing in research and development that allows us to innovate, develop and bring to market products and solutions that deliver the ever-increasing clinical precision and predictability that doctors expect with the speed and convenience their patients require.

- Creating demand and enabling patient conversion through targeted investments in advertising and public relations through social media, influencers and other forms of digital communications to encourage treatment by Invisalign trained doctors. We believe that well-designed, targeted sales and marketing promotions that build on our strong brand awareness allow us to differentiate our products and solutions from traditional and emerging competitors. In 2022, we continued to build on the success of the “Invis-is” consumer advertising campaign with creative content and influencers focused on teens and young adults. We expect to make further investments to create additional demand for Invisalign system treatment driving more consumers to dental professionals for those treatments.

- Pursuing new product lines that complement our doctor-prescribed principal products currently available in certain e-commerce and retail channels in the U.S. Similarly, in 2023 we expect to continue to focus on our doctor subscription plan and grow our underpenetrated share of the retainer business through strategic marketing campaigns focused on driving adoption and increasing market share in the U.S.

- Increasing global orthodontic utilization rates as doctors’ clinical confidence in the efficacy and predictability of the Invisalign system increases with advancements in products and technology and as patients and doctors demand treatments that emphasize convenience and safety through fewer visits and less invasive and quicker treatments. In addition, the teenage and younger market makes up 75% of the approximately 21 million total annual global orthodontic case starts each year. As we continue to emphasize the benefits of the Invisalign system for teenage and younger patient treatments through education, training and sales and marketing programs, we expect utilization rates to rise. However, our utilization rates will fluctuate from period to period due to a variety of factors, which may include seasonal trends in our business, consumer demand due to macroeconomic factors, office closures or slowdowns related to COVID-19-and adoption rates for new products and features.

Macroeconomic Challenges and Military Conflict in Ukraine

Our revenues are susceptible to fluctuations in macroeconomic conditions, in line with inflation, rising interest rates, threats of or actual recessions, fluctuations in currency exchange rates, supply chain challenges, market volatility, wars and military actions, and other factors, each of which impact customer confidence, consumer sentiment and demand. Many of these same factors are also impacting our costs through higher raw material prices, transportation costs, labor costs, supply and distribution operations and the operations of our suppliers. Additionally, many of our international operations are denominated in currencies other than the U.S. dollar and in 2022 were impacted, and may continue to be impacted, by macroeconomic slowing or contraction causing weakening against the U.S. dollar, which is negatively impacting our financial condition and results of operations. While we expect moderation of the strength of the dollar, we also expect the dollar to remain historically strong against many of these currencies. The nature and extent of the impact of these factors varies by time and region and remains uncertain and unpredictable.

The military conflict between Russia and Ukraine increased the unpredictability of the already uncertain macroeconomic conditions during 2022 and may continue to impact this unpredictability. While we continue to employ research and development personnel in Russia as well as certain sales, marketing and administrative personnel, the total number of employees in Russia was significantly reduced in 2022, complementing programs previously underway aimed at maintaining and growing our research and development operations and diversifying the facilities at which our personnel are located.

Although immaterial to our consolidated financial statements, our commercial business operations in Russia were significantly impacted by the conflict in 2022. Although we remain committed to providing continuity of care consistent with our values and ethical responsibility to patients who are in Invisalign treatment in Russia, we deemed it prudent to align the size of our commercial operations with the ongoing resources needed to perform those functions. Accordingly, in the fourth quarter of 2022, we initiated a restructuring plan to increase efficiencies across the organization and lower our overall cost structure, which reduced the number of employees and our commercial business operations in Russia. Refer to *Note 16 "Restructuring and Other Charges" of the Notes to Consolidated Financial Statements* for further details.

Our Board of Directors and its applicable committees receive regular updates from management regarding the military conflict between Russia and Ukraine and continue to provide oversight of the risks to our personnel, operations and other areas of strategic importance. Our management continues to closely monitor the situation and evaluate additional ways in which we can support our employees and operations.

COVID-19 Pandemic Update

Although there remains significant uncertainty surrounding the COVID-19 pandemic for regional economies, its global impact has gradually declined. During 2022, we experienced the impacts of the COVID-19 pandemic primarily in the Asia Pacific region, particularly in China, where lockdowns decreased economic activity throughout most of the year. With the easing of the restrictions in China in 2023 and the increased rate of infections, the impacts of the COVID-19 pandemic are likely to persist into 2023 and remain unpredictable, but we expect it to be at a lesser extent than in 2022. Nevertheless, comparing our financial results for the reporting periods of 2023 to the same reporting periods of 2022 or earlier may not be a useful means by which to evaluate our business and results of operations due to volatility in regional business environments caused by the pandemic.

Changing Product Preferences

As the markets for clear aligners and digital processes and workflows used to transform the practice of dentistry continue to mature, we anticipate customer and patient expectations and demands will evolve. We expect to meet customer demands with innovative treatment options that include more choices to address a wider scope of treatment goals and budgets based on our existing and new products. This may result in larger and unpredictable variations in geographic and product mix and selling prices with uncertain implications on our financial statements and business operations.

We strive to manage the challenges from the macroeconomic conditions, the conflict in Ukraine, COVID-19 and the evolution of our target markets by focusing on improving our operations, building flexibility and efficiencies in our processes, adjusting our business models to changing circumstances and offering products that meet market demand. Specifically, we are managing cost impacts through pricing actions, implementing cost saving measures and slowing hiring. We also continue to innovate and introduce new and enhanced products that augment our doctor customer and patient experiences.

Further discussion of the impact of these challenges on our business may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading *"Risk Factors."*

Key Financial and Operating Metrics

We measure our performance against these strategic priorities by the achievement of key financial and operating metrics. For the year ended December 31, 2022, our business operations reflect the following:

- Revenues of $3,734.6 million, a decrease of 5.5% year-over-year;
- Clear Aligner revenues of $3,072.6 million, a decrease of 5.4% year-over-year;
  - Americas Clear Aligner revenues of $1,458.8 million, a decrease of 5.6% year-over-year;
  - International Clear Aligner revenues of $1,349.0 million, a decrease of 10.0% year-over-year;
  - Clear Aligner volume decrease of 7.4% year-over-year and Clear Aligner volume decrease for teenage patients of 0.2% year-over-year;
- Imaging Systems and CAD/CAM Services revenues of $662.1 million, a decrease of 6.2% year-over-year;
- Income from operations of $642.6 million and operating margin of 17.2%;
- Effective tax rate of 39.6%;
- Net income of $361.6 million with diluted net income per share of $4.61;
- Cash, cash equivalents and marketable securities of $1,041.6 million as of December 31, 2022;
- Operating cash flow of $568.7 million;
- Capital expenditures of $291.9 million, predominantly related to increases in our manufacturing capacity and facilities; and

- Number of employees was 23,165 as of December 31, 2022, an increase of 2.8% year-over-year.

Other Statistical Data and Trends

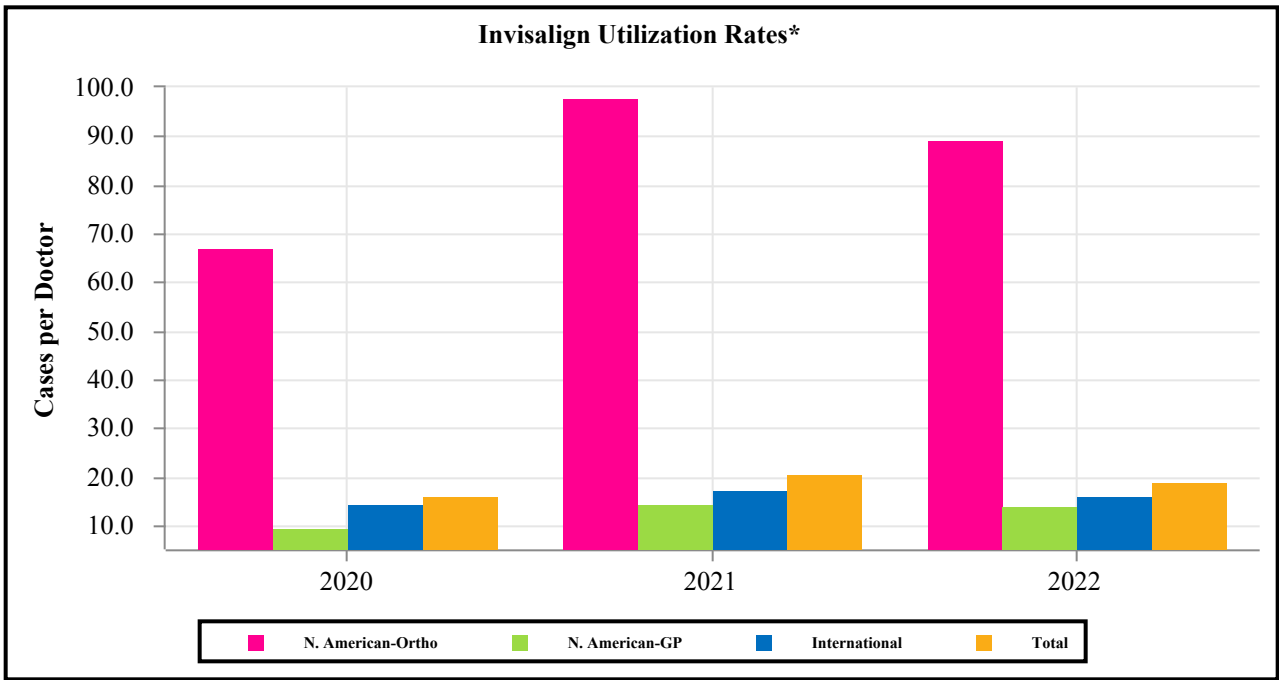
- As of December 31, 2022, over 14 million people worldwide have been treated with our Invisalign system. Management measures these results by comparing to the millions of people who can benefit from straighter teeth and uses this data to target opportunities to expand the market for orthodontics by educating consumers about the benefits of straighter teeth using the Invisalign system.

- For the fourth quarter of 2022, total Invisalign cases submitted with a digital scanner in the Americas increased to 92.5%, up from 89.1% in the fourth quarter of 2021 and international scans increased to 86.8%, up from 80.8% in the fourth quarter of 2021. For the fourth quarter of 2022, 97.4% of Invisalign cases submitted by North American orthodontists were submitted digitally.

- The total utilization rate in 2022 was 18.9 cases per doctor compared to 20.8 cases per doctor in 2021 and 16.1 cases per doctor in 2020. Our utilization rates have declined in 2022 due to the macroeconomic conditions, COVID-19 impacts, and other factors as described in the Trends and Uncertainties section above. In general, we expect utilization rates to rise over time although they are likely to fluctuate from period to period.

    - *North America:* The utilization rate among our North American orthodontist customers was 89.2 cases per doctor in 2022 compared to 98.1 cases per doctor in 2021 and 67.3 cases per doctor in 2020 and the utilization rate among our North American GP customers was 13.9 cases per doctor in 2022 compared to 14.3 cases per doctor in 2021 and 9.6 cases per doctor in 2020.

    - *International:* International doctor utilization rate was 16.2 cases per doctor in 2022 compared to 17.5 cases per doctor in 2021 and 14.5 cases per doctor in 2020.



* Invisalign utilization rates are calculated by the number of cases shipped divided by the number of doctors to whom cases were shipped. Our International region includes Europe, Middle East and Africa ("EMEA") and Asia Pacific ("APAC"). Latin America ("LATAM") is excluded from the International region based on its immateriality to the year; however is included in the Total utilization.

Results of Operations

Net Revenues by Reportable Segment

We group our operations into two reportable segments: Clear Aligner segment and Systems and Services segment.

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
    - Comprehensive Products include, but are not limited to, Invisalign Comprehensive and Invisalign First.
    - Non-Comprehensive Products include, but are not limited to, Invisalign Moderate, Lite and Express packages and Invisalign Go and Invisalign Go Plus.
    - Non-Case products include, but are not limited to, retention products, Invisalign training, adjusting tools used by dental professionals during the course of treatment and Invisalign Accessory Products that are complementary to our doctor-prescribed principal products such as aligner cases (clamshells), teeth whitening products, cleaning solutions (crystals, foam and other material) and other oral health products available in certain e-commerce channels in select markets. We also offer in the U.S. and Canada, a Doctor Subscription Program which is a monthly subscription program based on the doctor's monthly need for retention or limited treatment. The program allows doctors the flexibility to order both "touch-up" or retention aligners within their subscribed tier and is designed for a segment of experienced Invisalign trained doctors who are currently not regularly using our retainers or low-stage aligners.
- Our Systems and Services segment consists of our iTero intraoral scanning systems, which includes a single hardware platform and restorative or orthodontic software options. Our services include subscription software, disposables, rentals, leases, pay per scan services, as well as exocad's CAD/CAM software solutions that integrate workflows to dental labs and dental practices.

Net revenues for our Clear Aligner and Systems and Services segments by region for the year ended December 31, 2022, 2021 and 2020 are as follows (in millions):

	Year Ended December 31,				Year Ended December 31,			
Net Revenues	**2022**	**2021**	**Change**		**2021**	**2020**	**Change**	
Clear Aligner revenues:								
Americas	$ 1,458.8	$ 1,544.8	$ (85.9)	(5.6)%	$ 1,544.8	$ 1,010.2	$ 534.5	52.9 %
International	1,349.0	1,498.7	(149.7)	(10.0)%	1,498.7	965.4	533.2	55.2 %
Non-case	264.8	203.7	61.1	30.0 %	203.7	125.8	77.8	61.9 %
Total Clear Aligner net revenues	$ 3,072.6	$ 3,247.1	$ (174.5)	(5.4)%	$ 3,247.1	$ 2,101.5	$1,145.6	54.5 %
Systems and Services net revenues	662.1	705.5	(43.5)	(6.2)%	705.5	370.5	335.0	90.4 %
Total net revenues	$ 3,734.6	$ 3,952.6	$ (217.9)	(5.5)%	$ 3,952.6	$ 2,471.9	$1,480.6	59.9 %

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Clear Aligner Case Volume

Case volume data which represents Clear Aligner case shipments for the year ended December 31, 2022, 2021 and 2020 is as follows (in thousands):

	Year Ended December 31,				Year Ended December 31,			
	2022	**2021**	**Change**		**2021**	**2020**	**Change**	
Total case volume	2,358.7	2,547.7	(189.0)	(7.4)%	2,547.7	1,645.3	902.4	54.8 %

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Total net revenues decreased by $217.9 million in 2022 as compared to 2021, primarily due to unfavorable foreign exchange rates, a decrease in both Clear Aligner case volumes and scanner volumes, partially offset by increases in Clear Aligner non-case revenues, service revenues and an increase in Clear Aligner average selling price ("ASP").

Clear Aligner - Americas

Americas net revenues decreased by $85.9 million in 2022 as compared to 2021, primarily due to a decrease in case volumes of 9.4% which reduced net revenues by $145.3 million, partially offset by an increase in ASP which increased net revenues by $59.4 million. Higher ASP was mainly due to processing fees charged on most shipments and price increases in certain markets which increased net revenues by $54.2 million along with lower net deferrals which increased net revenues by $34.5 million. The increases in ASP were partially offset by unfavorable promotional discounts and sales credits which reduced net revenues by $25.1 million.

Clear Aligner - International

International net revenues decreased by $149.7 million in 2022 as compared to 2021 due to a 5.0% decrease in case volumes, which decreased net revenues by $75.1 million, and lower ASP, which decreased net revenues by $74.6 million. Lower ASP was largely due to unfavorable foreign exchange rates which resulted in lower net revenues of $150.6 million, a product mix shift to lower priced products which decreased net revenues by $60.5 million, and unfavorable promotional discounts which decreased net revenues $39.4 million. The decrease in ASP was partially offset by processing fees charged on most shipments which increased net revenues by $94.1 million and lower net deferrals which increased net revenues by $81.4 million.

Clear Aligner - Non-Case

Non-case net revenues increased by $61.1 million in 2022 compared to 2021 mainly due to increased volume for retention products across most regions primarily driven by Vivera retainers.

Systems and Services

Systems and Services net revenues decreased by $43.5 million in 2022 as compared to 2021 primarily due to a lower number of scanners sold which decreased net revenues by $97.1 million and lower scanner ASP which decreased net revenues by $9.0 million. The decreases were partially offset by higher service and other revenues which increased net revenues by $62.6 million mostly due to a larger scanner install base.

Cost of net revenues and gross profit (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Clear Aligner						
Cost of net revenues	$ 844.4	$ 772.7	$ 71.7	$ 772.7	$ 569.3	$ 203.4
% of net segment revenues	*27.5 %*	*23.8 %*		*23.8 %*	*27.1 %*	
Gross profit	$ 2,228.2	$ 2,474.4	$ (246.2)	$ 2,474.4	$ 1,532.1	$ 942.2
Gross margin %	*72.5 %*	*76.2 %*		*76.2 %*	*72.9 %*	
Systems and Services						
Cost of net revenues	$ 256.4	$ 244.5	$ 11.9	$ 244.5	$ 139.4	$ 105.1
% of net segment revenues	*38.7 %*	*34.7 %*		*34.7 %*	*37.6 %*	
Gross profit	$ 405.6	$ 461.0	$ (55.4)	$ 461.0	$ 231.1	$ 229.9
Gross margin %	*61.3 %*	*65.3 %*		*65.3 %*	*62.4 %*	
Total cost of net revenues	$ 1,100.9	$ 1,017.2	$ 83.6	$ 1,017.2	$ 708.7	$ 308.5
% of net revenues	*29.5 %*	*25.7 %*		*25.7 %*	*28.7 %*	
Gross profit	$ 2,633.8	$ 2,935.4	$ (301.6)	$ 2,935.4	$ 1,763.2	$ 1,172.1
Gross margin %	*70.5 %*	*74.3 %*		*74.3 %*	*71.3 %*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Cost of net revenues includes personnel-related costs including payroll and stock-based compensation for staff involved in the production process, the cost of materials, packaging, freight and shipping related costs, depreciation on capital equipment and facilities used in the production process, amortization of acquired intangible assets and training costs.

Clear Aligner

The gross margin percentage decreased in 2022 as compared to 2021 primarily due to a higher mix of additional aligners, higher freight costs and increased manufacturing spend as we continue to ramp our new manufacturing facility in Poland.

Systems and Services

The gross margin percentage decreased in 2022 as compared to 2021 primarily due to manufacturing inefficiencies from lower production volumes and lower ASP. These factors were partially offset by higher service revenues.

Selling, general and administrative (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Selling, general and administrative	$ 1,674.5	$ 1,708.6	$ (34.2)	$ 1,708.6	$ 1,200.8	$ 507.9
% of net revenues	*44.8 %*	*43.2 %*		*43.2 %*	*48.6 %*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Selling, general and administrative expense generally includes personnel-related costs, including payroll, stock-based compensation and commissions for our sales force, marketing and advertising expenses including media, market research, marketing materials, clinical education, trade shows and industry events, legal and outside service costs, equipment, software and maintenance costs, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and Information Technology ("IT").

Selling, general and administrative expense decreased in 2022 compared to 2021 primarily due to lower incentive compensation, lower advertising and marketing costs and lower allocations of corporate overhead expenses. These decreases were offset by higher salaries expenses, fringe benefits and stock-based compensation from increased headcount as well as higher equipment, software and maintenance costs.

Research and development (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Research and development	$ 305.3	$ 250.3	$ 54.9	$ 250.3	$ 175.3	$ 75.0
% of net revenues	*8.2 %*	*6.3 %*		*6.3 %*	*7.1 %*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Research and development expense generally includes personnel-related costs, including payroll and stock-based compensation, outside service costs associated with the research and development of new products and enhancements to existing products, software, equipment, material and maintenance costs, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and IT.

Research and development expense increased in 2022 compared to 2021 primarily due to higher salaries expense, fringe benefits and stock-based compensation as we continue to focus our investments in innovation and research in addition to higher allocations of corporate overhead expenses, outside services costs and equipment and materials costs. These increases were partially offset by lower incentive compensation.

Restructuring and other charges (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Restructuring and other charges	$ 11.5	$ —	$ 11.5	$ —	$ —	$ —
% of net revenues	*0.3 %*	*— %*		*— %*	*— %*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Restructuring and other charges includes $7.3 million of severance and related costs, in addition to lease termination charges and asset impairments.

Income from operations (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Clear Aligner						
Income from operations	$ 1,134.4	$ 1,325.9	$ (191.4)	$ 1,325.9	$ 768.0	$ 557.8
Operating margin %	*36.9 %*	*40.8 %*		*40.8 %*	*36.5 %*	
Systems and Services						
Income from operations	$ 179.8	$ 259.1	$ (79.4)	$ 259.1	$ 96.1	$ 163.1
Operating margin %	*27.2 %*	*36.7 %*		*36.7 %*	*25.9 %*	
Total income from operations [1]	$ 642.6	$ 976.4	$ (333.8)	$ 976.4	$ 387.2	$ 589.2
Operating margin %	*17.2 %*	*24.7 %*		*24.7 %*	*15.7 %*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

[1] Refer to *Note 15 "Segments and Geographical Information" of the Notes to Consolidated Financial Statements* for details on unallocated corporate expenses and the reconciliation to Consolidated Income from Operations.

Clear Aligner

Operating margin percentage decreased in 2022 compared to 2021 primarily due to lower gross margin.

Systems and Services

Operating margin percentage decreased in 2022 compared to 2021 primarily due to higher operating expenses as a percentage of net revenues as well as lower gross margin.

Interest income (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Interest income	$ 5.4	$ 3.1	$ 2.3	$ 3.1	$ 3.1	$ —
% of net revenues	*0.1 %*	*0.1 %*		*0.1 %*	*0.1 %*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Interest income generally includes interest earned on cash, cash equivalents and investment balances.

Interest income increased in 2022 compared to 2021 primarily due to higher interest rates during 2022, which was partially offset by the interest earned from the arbitration award related to our investment in SmileDirectClub in the first quarter of 2021.

Other income (expense), net (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Other income (expense), net	$ (48.9)	$ 32.9	$ (81.8)	$ 32.9	$ (11.3)	$ 44.3
% of net revenues	*(1.3)%*	*0.8 %*		*0.8 %*	*(0.5)%*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

Other income (expense), net, generally includes foreign exchange gains and losses, gains and losses on foreign currency forward contracts, interest expense, gains and losses on equity investments and other miscellaneous charges.

Other income (expense), net decreased in 2022 compared to 2021 primarily due to a $43.4 million gain associated to the arbitration award related to our investment in SmileDirectClub recognized in the first quarter of 2021 as well as $30.5 million of higher net foreign exchange losses from the weakening of international currencies against the U.S. dollar in 2022 as compared to 2021.

Provision for (benefit from) income taxes (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	Change	2021	2020	Change
Provision for (benefit from) income taxes	$ 237.5	$ 240.4	$ (2.9)	$ 240.4	$ (1,396.9)	$ 1,637.3
Effective tax rates	*39.6 %*	*23.7 %*		*23.7 %*	*(368.6)%*	

Changes and percentages are based on actual values. Certain tables may not sum or recalculate due to rounding.

The increase in our effective tax rate for the year ended December 31, 2022 compared to the same period in 2021 is primarily attributable to decreased earnings in low tax jurisdictions and an increase in the amount of foreign earnings subject to US tax in 2022. Additionally, a change in U.S. tax laws effective January 1, 2022 which requires capitalization and amortization of research and development expenses incurred after December 31, 2021 increased our effective tax rate for the year ended December 31, 2022.

During 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss subsidiary, where our EMEA regional headquarters is located beginning January 1, 2020. The transfer of intellectual property rights did not result in a taxable gain; however, it did result in a step-up of the Swiss tax deductible basis in the transferred assets, and accordingly, created a temporary difference between the book basis and the tax basis of such intellectual property rights. Consequently, this transaction resulted in the recognition of a deferred tax asset and related one-time tax benefit of approximately $1,493.5 million during the year ended December 31, 2020, which is the net impact of the deferred tax asset recognized as a result of the additional Swiss tax deductible basis in the transferred assets and certain costs related to the transfer of fixed assets and inventory. The amortization of this deferred tax asset depends on the profitability of our Swiss headquarters and the recognition of this tax benefit is allowed for a maximum recovery period of 15 years.

The U.S. Inflation Reduction Act of 2022 (“IRA”) was enacted in the United States on August 16, 2022. The IRA imposes a 15% alternative minimum tax on the financial statement income of certain corporations which is effective for tax years beginning after December 31, 2022, as well as a 1% excise tax on the net fair market value of stock repurchases made after December 31, 2022. Based upon our analysis of the IRA, we have determined there is no impact to our tax provision for the year ended December 31, 2022. We will continue to evaluate the impact of these tax law changes on future periods.

Liquidity and Capital Resources

Liquidity and Trends

As of December 31, 2022 and 2021, we had the following cash and cash equivalents and short-term and long-term marketable securities (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents	$ 942,050	$ 1,099,370
Marketable securities, short-term	57,534	71,972
Marketable securities, long-term	41,978	125,320
Total	$ 1,041,562	$ 1,296,662

As of December 31, 2022 and 2021, approximately $653.7 million and $713.8 million, respectively, of cash, cash equivalents and marketable securities were held by our foreign subsidiaries. We intend to continue reinvesting our foreign subsidiary earnings indefinitely and expect the additional costs upon repatriation of these foreign earnings not to be significant. We generate sufficient domestic operating cash flow and have access to external funding under our $300.0 million revolving line of credit. We believe that our current cash balances and the borrowing capacity under our credit facility, if necessary, will be sufficient to fund our business for at least the next 12 months.

The sanctions against Russian banks or international bank messaging systems due to the military conflict between Ukraine and Russia could impact our ability to access our cash in Russia but would not materially impact our liquidity position. As of December 31, 2022, cash and cash equivalents domiciled in Russia, which is required to fund their current operating requirements, represent approximately 2.6% of our total cash, cash equivalents and marketable securities.

Our material cash requirements as of December 31, 2022 are as below:

- Our purchase commitments for goods and services, excluding capital expenditures, totaled $1,151.7 million, of which $860.8 million will be payable within the next 12 months. These commitments primarily relate to agreements with contract manufacturers and suppliers, sales and marketing services, research and development services and technological services.

- We expect our investments in capital expenditures to exceed $200.0 million for the next 12 months. Capital expenditures primarily relate to building construction and improvements as well as additional manufacturing capacity due to international expansion. Despite the challenging market conditions, we intend to expand our investments in research and development, manufacturing, treatment planning, sales and marketing operations to meet actual and anticipated local and regional demands.

- We have future operating lease payments of $158.3 million, which includes $14.3 million for leases that have not yet commenced as of December 31, 2022. Refer to *Note 4* "*Leases*" *of the Notes to Consolidated Financial Statements* for details on the lease payments.

- We have $249.9 million available for repurchase under the stock repurchase program authorized by our Board of Directors in May 2021 ("May 2021 Repurchase Program"). Our stock repurchase program is subject to periodic evaluations to determine when and if repurchases are in the best interests of our stockholders, taking into account prevailing market conditions. Refer to *Note 10* "*Common Stock Repurchase Programs*" *of the Notes to Consolidated Financial Statements* for details on our stock repurchase programs. Subsequent to the fourth quarter, in January 2023, our Board of Directors authorized a new plan to repurchase up to $1.0 billion of our common stock. Additionally, in February 2023, we entered into an ASR to repurchase $250.0 million of our common stock, completing our 2021 Repurchase Program. Under the Inflation Reduction Act of 2022, effective January 1, 2023, excise tax of 1% is applicable to stock repurchases. We are currently evaluating the impact of this provision, if any, on our results of operations and cash flows.

Sources and Use of Cash

The following table summarizes our Consolidated Statements of Cash Flows for the year ended December 31, 2022, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net cash provided by (used in):			
Operating activities	$ 568,732	$ 1,172,544	$ 662,174
Investing activities	(213,316)	(563,430)	(231,506)
Financing activities	(501,686)	(458,332)	(30,808)
Effects of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(11,514)	(12,117)	10,480
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (157,784)	$ 138,665	$ 410,340

Operating Activities

For the year ended December 31, 2022, cash flows from operations of $568.7 million resulted primarily from our net income of approximately $361.6 million as well as the following:

Significant adjustments to net income

- Stock-based compensation of $133.4 million related to equity awards granted to employees and directors; and
- Depreciation and amortization of $125.8 million related to our investments in property, plant and equipment and intangible assets.

Significant changes in working capital

- Increase of $241.9 million in deferred revenues due to the deferral of revenue on shipments over the period as well as timing of revenue recognition;
- Increase of $130.1 million in inventories primarily due to lower shipment volumes over the period in addition to our efforts to manage stock at appropriate levels as required; and

- Decrease of $121.9 million in accrued and other long-term liabilities primarily due to the payment of our 2021 corporate bonus as well as timing payment of other activities.

For the year ended December 31, 2021, cash flows from operations of $1,172.5 million resulted primarily from our net income of approximately $772.0 million as well as the following:

Significant adjustments to net income

- Stock-based compensation of $114.3 million related to equity awards granted to employees and directors;
- Depreciation and amortization of $108.7 million related to our investments in property, plant and equipment and intangible assets; and
- Gain related to our SDC arbitration award of $43.4 million.

Significant changes in working capital

- Increase of $462.6 million in deferred revenues primarily related to increased case volumes in our Clear Aligner segment, increased scanner volumes in our Systems and Services segment and timing of revenue recognition;
- Increase of $262.1 million in accounts receivable which is primarily a result of the increase in our sales;
- Increase of $158.5 million in accrued and other long-term liabilities and an increase of $124.6 million in prepaid expenses and other assets due to the timing of prepayment and activities; and
- Increase of $112.5 million in inventories to support our demand, including safety stock, due to shipping delays during the COVID-19 pandemic as well as long lead times with our suppliers.

Investing Activities

Net cash used in investing activities was $213.3 million for the year ended December 31, 2022 which primarily consisted of purchases of property, plant and equipment of $291.9 million, purchases of marketable securities of $28.0 million and $12.3 million cash paid relating to a business acquisition. These outflows were partially offset by sales and maturities of marketable securities of $121.1 million.

Net cash used in investing activities was $563.4 million for the year ended December 31, 2021 and primarily consisted of purchases of property, plant and equipment of $401.1 million and purchases of marketable securities of $200.9 million, which were partially offset by $43.4 million of proceeds from our SDC arbitration award.

Financing Activities

Net cash used in financing activities was $501.7 million for the year ended December 31, 2022 which consisted of payments related to our common stock repurchases of $475.0 million and payroll taxes paid for equity awards through share withholdings of $52.8 million, which were partially offset by $26.1 million of proceeds from the issuance of common stock under our employee stock purchase plan.

Net cash used in financing activities was $458.3 million for the year ended December 31, 2021 which consisted of payments related to our accelerated stock repurchase arrangements of $375.0 million and payroll taxes paid for equity awards through share withholdings of $108.9 million which were partially offset by $25.6 million of proceeds from the issuance of common stock.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses and disclosures at the date of the financial statements. We evaluate our estimates on an on-going basis and use authoritative pronouncements, historical experience and other assumptions as the basis for making the estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies and estimates affect our more significant judgments used in the preparation of our consolidated financial statements. For further information on all of our significant accounting policies, see *Note 1* "*Summary of Significant Accounting Policies*" *of the Notes to Consolidated Financial Statements* under *Item 8*.

Revenue Recognition

Our revenues are derived primarily from the sale of aligners, scanners, and services from our Clear Aligner and Systems and Services segments. We enter into sales contracts that may consist of multiple distinct performance obligations where certain performance obligations of the sales contract are not delivered in one reporting period. We measure and allocate revenues according to ASC 606-10, *"Revenues from Contracts with Customers."*

Determining the standalone selling price ("SSP") in order to allocate consideration from the contract to the individual performance obligations is the result of various factors, such as changing trends and market conditions, historical prices, costs, and gross margins. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenues recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on our financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

We allocate revenues for each clear aligner treatment plan based on each unit's SSP. Management considers a variety of factors such as same or similar product historical sales, costs, and gross margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. In addition to historical data, we take into consideration changing trends and market conditions. For treatment plans with multiple options, we also consider usage rates, which is the number of times a customer is expected to order more aligners after the initial shipment. Our process for estimating usage rates requires significant judgment and evaluation of inputs, including historical usage data by region, country and channel.

We estimate the SSP of each element in a scanner system and services sale taking into consideration same or similar product historical prices as well as our discounting strategies.

Unfulfilled Performance Obligations for Clear Aligners and Scanners

The estimated revenues expected to be recognized in the future related to our unfulfilled performance obligations, including deferred revenues and backlog, as of December 31, 2022 is $1,515.4 million. This estimate includes both product and service unfulfilled performance obligations and the time range reflects our best estimate of when we will transfer control to the customer and may change based on customer usage patterns, timing of shipments, readiness of customers' facilities for installation, and manufacturing availability some of which involve significant judgement. Generally, our deferred revenue will be recognized over a period of one to five years.

Goodwill and Finite-Lived Acquired Intangible Assets

Goodwill and acquired intangible assets with finite lives are subject to impairment testing and are reviewed for impairment when events or circumstances indicate that the carrying value of an asset is not recoverable and the carrying amount exceeds its fair value. We evaluate the recoverability of the carrying value of these identifiable intangible assets based on estimated undiscounted cash flows to be generated from such assets. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, we may be required to record impairment charges.

Assumptions and estimates about future values and remaining useful lives of our acquired intangible assets are complex and subjective. They can be affected by external factors such as industry and economic trends and internal factors such as changes in our business strategy and internal forecasts. Our ongoing consideration of all these factors could result in impairment charges in the future.

If we were to have impairments to goodwill or finite-lived acquired intangible assets, it could adversely affect our operating results. During the fiscal year 2022 and 2021, we did not have any impairment charges related to our goodwill or acquired intangible assets.

Accounting for Income Taxes

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. The evaluation of our uncertain tax positions involves significant judgment in the interpretation and application of U.S. GAAP and complex domestic and international tax laws related to the allocation of international taxation rights between countries. We are also required to evaluate the realizability of our deferred tax assets on an ongoing basis in accordance with U.S. GAAP, which requires the assessment of both of our historical and future performance as well as other relevant factors. Realization of our deferred tax assets is dependent on our ability to generate future taxable income which is determined based on assumptions such as

estimated growth rates in revenues, gross margins, future cash flows and discount rates. The accuracy of these estimates could be affected by unforeseen events or actual results, and the sustainability of our future tax benefits is dependent upon the acceptance of these valuation estimates and assumptions by the taxing authorities.

Accounting for Legal Proceedings and Litigation

Estimates of probable losses resulting from litigation are inherently difficult to make, particularly when the matters are in early procedural stages with incomplete facts and information. The final outcome of legal proceedings is dependent on many variables difficult to predict and, therefore, the ultimate cost to entirely resolve such matters may be materially different than the amount of current estimates. Consequently, new information or changes in judgments and estimates could have a material adverse effect on our business, financial condition, and results of operations or cash flows.

Recent Accounting Pronouncements

See *Note 1* "*Summary of Significant Accounting Policies" of the Notes to Consolidated Financial Statements* in *Item 8* for a discussion of recent accounting pronouncements, including the expected dates of adoption and estimated effects on results of operations and financial condition, which is incorporated herein.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

In the normal course of business, we are exposed to interest rate, foreign currency exchange and inflation risks that could impact our financial position and results of operations. In addition, we are subject to the broad market risk that is created by the global market disruptions and uncertainties resulting from macroeconomic challenges, the military conflict between Russia and Ukraine and the COVID-19 pandemic. Further discussion on these risks may be found in *Item 1A* of this Annual Report on Form 10-K under the heading *"Risk Factors"*.

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our investments are fixed-rate short-term and long-term securities. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates, and, as a result, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. As of December 31, 2022, we had approximately $99.5 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. As of December 31, 2022, we are not subject to risks from immediate interest rate increases on our unsecured revolving line of credit facility.

Currency Rate Risk

As a result of our international business activities, our financial results have been affected by factors such as changes in foreign currency exchange rates as well as economic conditions in foreign markets, and there is no assurance that exchange rate fluctuations will not harm our business in the future. We generally sell our products in the local currency of the respective countries. This provides some natural hedging because most of the subsidiaries' operating expenses are generally denominated in their local currencies.

We enter into foreign currency forward contracts for currencies where we have exposures, primarily the Euro, Chinese Yuan, Polish Zloty and Canadian Dollar, to minimize the short-term impact of foreign currency exchange rate fluctuations on cash and certain trade and intercompany receivables and payables. These forward contracts are not designated as hedging instruments and are generally one month in original maturity and are marked to market through earnings every period. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. We do not enter into foreign currency forward contracts for trading or speculative purposes. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates. It is difficult to predict the impact forward contracts could have on our results of operations.

Although we will continue to monitor our exposure to currency fluctuations, and, where appropriate, may use forward contracts to minimize the effect of these fluctuations, the impact of an aggregate change of 10% in foreign currency exchange rates relative to the U.S. dollar on our results of operations and financial position could be material.

Military Conflict between Russia and Ukraine

Beginning 2022, the military conflict between Russia and Ukraine has continued to escalate and create challenges to already uncertain macroeconomic conditions. As of December 31, 2022, we do not expect these events to have any material impact on our operations. Our Russia net revenues as a percentage of our consolidated net revenues and our assets domiciled in Russia, including cash and cash equivalents, as a percentage of our total assets, are immaterial.

Inflation Risk

The economy has been impacted by certain macroeconomic challenges which have contributed to a rising inflationary trend that have impacted both our revenues and costs globally, and which we expect will continue into the foreseeable future. If our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. There can be no assurance that our results of operations and financial condition will not be materially impacted by inflation in the future.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of Align is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed by, or under supervision of, our CEO and CFO, and effected by the board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Align;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of Align are being made only in accordance with authorizations of management and directors of Align; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of Align's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Based on our assessment, management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective based on criteria in *Internal Control - Integrated Framework (2013) issued by the COSO*.

The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

/s/ JOSEPH M. HOGAN

Joseph M. Hogan

President and Chief Executive Officer

February 27, 2023

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Executive Vice President, Global Finance

February 27, 2023

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Align Technology, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Align Technology, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, of comprehensive income, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes and financial statement schedule listed in the index appearing under Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Report of Management on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition – Determination of Standalone Selling Price of Distinct Performance Obligations in Clear Aligner Contracts

As described in Notes 1 and 15 to the consolidated financial statements, the Company recognized net revenues of $3.1 billion from its Clear Aligner segment for the year ended December 31, 2022. The Company enters into contracts ("treatment plans") that involve multiple future performance obligations. Management identifies a performance obligation as distinct if both of the following criteria are met: the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. Management allocates revenues for each treatment plan based on each unit's standalone selling price. Management considers a variety of factors such as same or similar product historical sales, costs, and gross margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. In addition to historical data, they take into consideration changing trends and market conditions. Management also considers usage rates, which is the number of times a customer is expected to order additional aligners. Management's process for estimating usage rates requires significant judgment and evaluation of inputs, including historical usage data by region, country and channel.

The principal considerations for our determination that performing procedures related to revenue recognition and the determination of standalone selling price of distinct performance obligations in Clear Aligner contracts is a critical audit matter are the significant judgment by management in determining the estimate of standalone selling price, which includes significant assumptions related to usage rates for each distinct performance obligation. This in turn led to significant auditor judgment, subjectivity, and effort in performing procedures to evaluate management's determination of the estimates of standalone selling price and usage rates for each distinct performance obligation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to revenue recognition, including controls over the determination of standalone selling price for each distinct performance obligation in the Company's Clear Aligner contracts. These procedures also included, among others, (i) testing management's process for determining the estimate of standalone selling price, which included testing the completeness and accuracy of inputs used and evaluating the reasonableness of factors considered by management related to same or similar product historical sales and usage rates, and (ii) testing management's process for estimating usage rates, which included evaluating the reasonableness of inputs evaluated by management related to historical usage data by region, country and channel.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 27, 2023

We have served as the Company's auditor since 1997.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2022	2021	2020
Net revenues	$ 3,734,635	$ 3,952,584	$ 2,471,941
Cost of net revenues	1,100,860	1,017,229	708,706
Gross profit	2,633,775	2,935,355	1,763,235
Operating expenses:			
Selling, general and administrative	1,674,469	1,708,640	1,200,757
Research and development	305,258	250,315	175,307
Restructuring and other charges	11,453	—	—
Total operating expenses	1,991,180	1,958,955	1,376,064
Income from operations	642,595	976,400	387,171
Interest income and other income (expense), net:			
Interest income	5,367	3,103	3,125
Other income (expense), net	(48,905)	32,920	(11,347)
Total interest income and other income (expense), net	(43,538)	36,023	(8,222)
Net income before provision for (benefit from) income taxes	599,057	1,012,423	378,949
Provision for (benefit from) income taxes	237,484	240,403	(1,396,939)
Net income	$ 361,573	$ 772,020	$ 1,775,888
Net income per share:			
Basic	$ 4.62	$ 9.78	$ 22.55
Diluted	$ 4.61	$ 9.69	$ 22.41
Shares used in computing net income per share:			
Basic	78,190	78,917	78,760
Diluted	78,420	79,670	79,230

The accompanying notes are an integral part of these consolidated financial statements.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Net income	$ 361,573	$ 772,020	$ 1,775,888
Other comprehensive income (loss):			
Change in foreign currency translation adjustment, net of tax	(11,480)	(38,680)	44,383
Change in unrealized gains (losses) on investments, net of tax	(3,130)	(495)	(194)
Other comprehensive income (loss)	(14,610)	(39,175)	44,189
Comprehensive income	$ 346,963	$ 732,845	$ 1,820,077

The accompanying notes are an integral part of these consolidated financial statements.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 942,050	$ 1,099,370
Marketable securities, short-term	57,534	71,972
Accounts receivable, net of allowance for doubtful accounts of $10,343 and $9,245, respectively	859,685	897,198
Inventories	338,752	230,230
Prepaid expenses and other current assets	226,370	195,305
Total current assets	2,424,391	2,494,075
Marketable securities, long-term	41,978	125,320
Property, plant and equipment, net	1,231,855	1,081,926
Operating lease right-of-use assets, net	118,880	121,257
Goodwill	407,551	418,547
Intangible assets, net	95,720	109,709
Deferred tax assets	1,571,746	1,533,767
Other assets	55,826	57,509
Total assets	$ 5,947,947	$ 5,942,110
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 127,870	$ 163,886
Accrued liabilities	454,374	607,315
Deferred revenues	1,343,643	1,152,870
Total current liabilities	1,925,887	1,924,071
Income tax payable	124,393	118,072
Operating lease liabilities	100,334	102,656
Other long-term liabilities	195,975	174,597
Total liabilities	2,346,589	2,319,396
Commitments and contingencies (Notes 7 and 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, $0.0001 par value (200,000 shares authorized; 77,267 and 78,710 issued and outstanding, respectively)	8	8
Additional paid-in capital	1,044,946	999,006
Accumulated other comprehensive income (loss), net	(10,284)	4,326
Retained earnings	2,566,688	2,619,374
Total stockholders' equity	3,601,358	3,622,714
Total liabilities and stockholders' equity	$ 5,947,947	$ 5,942,110

The accompanying notes are an integral part of these consolidated financial statements.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
	Shares	Amount				
Balance as of December 31, 2019	78,433	$ 8	$ 906,937	$ (688)	$ 439,912	$ 1,346,169
Net income	—	—	—	—	1,775,888	1,775,888
Net change in unrealized gains (losses) from investments	—	—	—	(194)	—	(194)
Net change in foreign currency translation adjustment	—	—	—	44,383	—	44,383
Issuance of common stock relating to employee equity compensation plans	427	—	20,314	—	—	20,314
Tax withholdings related to net share settlements of equity awards	—	—	(51,122)	—	—	(51,122)
Stock-based compensation	—	—	98,427	—	—	98,427
Balance as of December 31, 2020	78,860	8	974,556	43,501	2,215,800	3,233,865
Net income	—	—	—	—	772,020	772,020
Net change in unrealized gains (losses) from investments	—	—	—	(495)	—	(495)
Net change in foreign currency translation adjustment	—	—	—	(38,680)	—	(38,680)
Issuance of common stock relating to employee equity compensation plans	442	—	25,623	—	—	25,623
Tax withholdings related to net share settlements of equity awards	—	—	(108,917)	—	—	(108,917)
Common stock repurchased and retired	(592)	—	(6,592)	—	(368,446)	(375,038)
Stock-based compensation	—	—	114,336	—	—	114,336
Balance as of December 31, 2021	78,710	8	999,006	4,326	2,619,374	3,622,714
Net income	—	—	—	—	361,573	361,573
Net change in unrealized gains (losses) from investments	—	—	—	(3,130)	—	(3,130)
Net change in foreign currency translation adjustment	—	—	—	(11,480)	—	(11,480)
Issuance of common stock relating to employee equity compensation plans	305	—	26,149	—	—	26,149
Tax withholdings related to net share settlements of equity awards	—	—	(52,799)	—	—	(52,799)
Common stock repurchased and retired	(1,748)	—	(20,777)	—	(414,259)	(435,036)
Equity forward contract related to accelerated stock repurchase	—	—	(40,000)	—	—	(40,000)
Stock-based compensation	—	—	133,367	—	—	133,367
Balance as of December 31, 2022	77,267	$ 8	$1,044,946	$ (10,284)	$2,566,688	$ 3,601,358

The accompanying notes are an integral part of these consolidated financial statements.

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2022	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 361,573	$ 772,020	$1,775,888
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred taxes	(39,495)	15,455	(1,491,577)
Depreciation and amortization	125,793	108,729	93,538
Stock-based compensation	133,367	114,336	98,427
Non-cash operating lease cost	30,520	26,807	22,467
Arbitration award gain	—	(43,403)	—
Other non-cash operating activities	41,288	24,363	33,743
Changes in assets and liabilities, net of effects of acquisitions:			
Accounts receivable	21,549	(262,066)	(139,777)
Inventories	(130,097)	(112,450)	(29,110)
Prepaid expenses and other assets	(65,514)	(124,626)	(21,130)
Accounts payable	(36,523)	19,747	52,206
Accrued and other long-term liabilities	(121,942)	158,543	42,168
Long-term income tax payable	6,327	12,449	(2,802)
Deferred revenues	241,886	462,640	228,133
Net cash provided by operating activities	568,732	1,172,544	662,174
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisitions, net of cash acquired	(12,304)	(8,002)	(420,788)
Purchase of property, plant and equipment	(291,900)	(401,098)	(154,916)
Purchase of marketable securities	(28,002)	(200,928)	(5,341)
Proceeds from maturities of marketable securities	23,785	498	42,641
Proceeds from sales of marketable securities	97,316	3,114	278,817
Repayment on unsecured promissory note	—	4,594	26,925
Proceeds from arbitration award	—	43,403	—
Other investing activities	(2,211)	(5,011)	1,156
Net cash used in investing activities	(213,316)	(563,430)	(231,506)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	26,149	25,623	20,314
Common stock repurchases	(435,036)	(375,038)	—
Payment for equity forward contract related to accelerated stock repurchase	(40,000)	—	—
Payroll taxes paid upon the vesting of equity awards	(52,799)	(108,917)	(51,122)
Net cash used in financing activities	(501,686)	(458,332)	(30,808)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(11,514)	(12,117)	10,480
Net (decrease) increase in cash, cash equivalents, and restricted cash	(157,784)	138,665	410,340
Cash, cash equivalents, and restricted cash at beginning of year	1,100,139	961,474	551,134
Cash, cash equivalents, and restricted cash at end of year	$ 942,355	$1,100,139	$ 961,474

The accompanying notes are an integral part of these consolidated financial statements.

Note 1. Summary of Significant Accounting Policies

Business Description

Align Technology, Inc. ("We", "Our", "Align") is a global medical device company primarily engaged in the design, manufacture and marketing of Invisalign® clear aligners for the treatment of malocclusions, or the misalignment of teeth, by orthodontists and general dental practitioners ("GPs"), Vivera® retainers for retention, iTero® intraoral scanners and services for dentistry, and exocad® computer-aided design and computer-aided manufacturing ("CAD/CAM") software for dental laboratories and dental practitioners. Our vision and strategy is to revolutionize orthodontic and restorative dentistry through digital treatment planning and implementation using our Align Digital Platform™, an integrated suite of proprietary technologies and services designed to deliver a seamless, end-to-end solution for patients and consumers, orthodontists and GPs and lab partners. We strive to achieve our vision and strategy through key objectives made possible with the proprietary technologies and services of the Align Digital Platform to establish: clear aligners as the principal solution for the treatment of malocclusions with the Invisalign System as the treatment solution of choice by orthodontists, GPs and patients globally, our intraoral scanners as the preferred scanning technology for digital dental scans, and our exocad CAD/CAM software as the dental restorative solution of choice for dental labs. Our corporate headquarters is located in Tempe, Arizona and we have offices worldwide. Our Americas regional headquarters is located in Raleigh, North Carolina; our European, Middle East and Africa ("EMEA") regional headquarters is located in Rotkreuz, Switzerland; and our Asia Pacific ("APAC") regional headquarters is located in Singapore. We have two operating segments: (1) Clear Aligner, known as the Invisalign system, and (2) Imaging Systems and CAD/CAM services ("Systems and Services"), known as the iTero intraoral scanner and CAD/CAM services.

Basis of Presentation and Preparation

The consolidated financial statements include the accounts of Align and our wholly-owned subsidiaries after elimination of intercompany transactions and balances.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles ("GAAP") in the United States of America ("U.S.") requires our management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, useful lives of intangible assets and property and equipment, long-lived assets and goodwill, income taxes, contingent liabilities, the fair values of financial instruments, stock-based compensation and the valuation of investments in privately held companies among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

Fair Value of Financial Instruments

Fair value is an exit price, representing the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We use the GAAP fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. This hierarchy requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value:

Level 1 - Quoted (unadjusted) prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. We obtain fair values for our Level 2 investments. Our custody bank and asset managers independently use professional pricing services to gather pricing data which may include quoted market prices for identical or comparable financial instruments, or inputs other than quoted prices that are observable either directly or indirectly, and we are ultimately responsible for these underlying estimates.

Level 3 - Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

Cash and Cash Equivalents

We consider currency on hand, demand deposits, time deposits, and all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are held in various financial institutions in the U.S. and internationally.

Restricted Cash

The restricted cash primarily consists of funds reserved for legal requirements. Restricted cash balances are primarily included in other assets within our Consolidated Balance Sheets.

Marketable Securities

Our marketable securities consist of marketable debt securities which are classified as available-for-sale and are carried at fair value. Our fixed-income securities investment portfolio allows for investments with a maximum effective maturity of up to 40 months on any individual security. Marketable securities classified as current assets have maturities within one year from the balance sheet date. Unrealized gains or losses on such securities are included in accumulated other comprehensive income (loss), net ("AOCI") in stockholders' equity. Realized gains and losses from sales and maturities of all such securities are reported in earnings and computed using the specific identification cost method.

All of our marketable securities are subject to a periodic impairment review. We evaluate if an allowance for credit loss is necessary by considering available information relevant to the collectibility of the security and information about credit rating changes, past events, current conditions, and reasonable and supportable forecasts. Any allowance for credit loss is recorded as a charge to other income (expense), net, in our Consolidated Statement of Operations. If we have an intent to sell, or if it is more likely than not that we will be required to sell the security in an unrealized loss position before recovery of its amortized cost basis, we will write down the security to its fair value and record the corresponding charge as a component of other income (expense), net in our Consolidated Statement of Operations.

Variable Interest Entities

We evaluate whether an entity in which we have made an investment is considered a variable interest entity ("VIE"). If we determine we are the primary beneficiary of a VIE, we would consolidate the VIE into our financial statements. In determining if we are the primary beneficiary, we evaluate whether we have the power to direct the activities that most significantly impact the VIE's economic performance and the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE. Our evaluation includes identification of significant activities and an assessment of our ability to direct those activities based on governance provisions and arrangements to provide or receive product and process technology, product supply, operations services, equity funding, financing, and other applicable agreements and circumstances. Our assessments of whether we are the primary beneficiary of a VIE require significant assumptions and judgments. We have concluded that we are not the primary beneficiary of our VIE investments; therefore, we do not consolidate their results into our consolidated financial statements.

Investments in Privately Held Companies

Our investments in privately held companies in which we cannot exercise significant influence and do not own a majority equity interest or otherwise control are accounted for under the measurement alternative. Under the measurement alternative, the carrying value of our equity investment is adjusted to fair value for observable transactions for identical or similar investments of the same issuer. Investments in equity securities are reported on our Consolidated Balance Sheet as other assets, and we periodically evaluate them for impairment. We record any change in carrying value of our equity securities, in other income (expense), net in our Consolidated Statement of Operations. The carrying value of our equity investments in privately held companies without readily determinable fair values were not material as of December 31, 2022 or 2021 and the associated adjustments to the carrying values of the investments were not material during the year ended December 31, 2022, 2021 and 2020.

Derivative Financial Instruments

We enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations associated with certain assets and liabilities. These forward contracts are not designated as hedging instruments. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. We do not enter into foreign currency forward contracts for trading or speculative purposes. The net gain or loss from the settlement of these foreign currency forward contracts is recorded in other income (expense), net in the Consolidated Statement of Operations.

Foreign Currency

For our international subsidiaries, we analyze on an annual basis or more often if necessary, if a significant change in facts and circumstances indicate that the functional currency has changed. For international subsidiaries where the local currency is the functional currency, adjustments from translating financial statements from the local currency to the U.S. dollar reporting currency are recorded as a separate component of AOCI in the stockholders' equity section of the Consolidated Balance Sheet. This foreign currency translation adjustment reflects the translation of the balance sheet at period end exchange rates, and the income statement at the transaction date or average exchange rate in effect during the period. The foreign currency revaluation that are derived from monetary assets and liabilities stated in a currency other than functional currency are included in other income (expense), net. For the year ended December 31, 2022, 2021 and 2020, we had foreign currency net gains (losses) of $(43.8) million, $(13.3) million and $6.8 million, respectively.

Certain Risks and Uncertainties

We are subject to risks including, but not limited to, global and regional economic market conditions, inflation, fluctuations in foreign currency exchange rates, changes in consumer confidence and demand, increased competition, dependence on key personnel, protection and litigation of proprietary technology, shifts in taxable income between tax jurisdictions and compliance with regulations of the U.S. Food and Drug Administration ("FDA") and similar international agencies. Further, our operations globally have been impacted by the COVID-19 pandemic. Although its impact has been gradually declining, we continue to be exposed to risks and uncertainties posed by it which varies by geographic regions at different levels. The extent to which our business could be impacted in the future by the pandemic is highly uncertain and difficult to predict.

Our cash and investments are held primarily by five financial institutions. Financial instruments which potentially expose us to concentrations of credit risk consist primarily of cash equivalents and marketable securities. We invest excess cash primarily in money market funds, corporate bonds, asset-backed securities, municipal bonds and U.S. government agency bonds and treasury bonds and periodically evaluate them for credit losses. Such credit losses have not been material to our financial statements.

We purchase certain inventory from sole suppliers. Additionally, we rely on a limited number of hardware manufacturers. The inability of any supplier or manufacturer to fulfill our supply requirements could materially and adversely impact our future operating results.

Accounts Receivable, net

Trade accounts receivable are recorded at the invoiced amount. Accounts receivable, net includes allowances for doubtful accounts for any potentially uncollectible amounts. We periodically assess the adequacy of the allowance for doubtful accounts by reviewing the accounts receivable on a collective basis by considering factors such as aging of the receivables and customers' expected ability to pay, and on an individual basis for specific customers with known disputes or collectability issues. In determining the amount of the allowance for doubtful accounts, we also evaluate the creditworthiness of customers, current market conditions and forecasts of future economic conditions to make any adjustments. Actual write-offs have not materially differed from the estimated allowances. No individual customer accounted for 10% or more of our accounts receivable at December 31, 2022 or 2021 or net revenues for the year ended December 31, 2022, 2021 or 2020.

In 2022, we entered into factoring transactions on a non-recourse basis with financial institutions to sell certain of our non-U.S. accounts receivable. We account for these transactions as sales of accounts receivables and include the cash proceeds as a part of our cash flows from operations in the Consolidated Statements of Cash Flows. Total accounts receivable sold under the factoring arrangements was $37.0 million during the year ended December 31, 2022. Factoring fees on the sales of receivables were recorded in other income (expense), net in our Consolidated Statement of Operations and were not material.

Inventories

Inventories are valued at the lower of cost or net realizable value, with cost computed using standard cost which approximates actual cost on a first-in-first-out basis. Excess and obsolete inventories are determined primarily based on future demand forecasts, and write-downs of excess and obsolete inventories are recorded as a component of cost of net revenues.

Property, Plant and Equipment, net

Property, plant and equipment, net are stated at historical cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Construction in progress is related to the construction or development of property (including land) and equipment that have not yet been placed in service for their intended use. Upon sale or retirement, the asset's cost and related accumulated depreciation are removed from the balance sheet and any related gains or losses are reflected in income from operations. Maintenance and repairs are expensed as incurred. Refer to *Note 3 "Balance Sheet Components" of the Notes of Consolidated Financial Statements* for details on estimated useful lives.

Leases - Lessee

We determine if an arrangement is a lease at inception. Leases with a term of 12 months or less are not recorded on the balance sheet. Right-of-use ("ROU") assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. We use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments as the rate implicit in our leases is not readily determinable. We determine lease terms as the noncancellable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. We have lease agreements with lease and non-lease components which are accounted for as a single lease component. Payments under our lease arrangements are primarily fixed; however, certain lease agreements contain variable payments which are expensed as incurred and not included in the operating lease ROU assets and liabilities.

Business Combinations

We allocate the fair value of the purchase consideration to the assets acquired and liabilities assumed based on their estimated fair values at the acquisition date. When determining the fair value of assets acquired and liabilities assumed, management is required to make certain estimates and assumptions, especially with respect to intangible assets. The estimates and assumptions used in valuing intangible assets include, but are not limited to, the amount and timing of projected future cash flows including forecasted revenues, the discount rate used to determine the present value of these cash flows, and the determination of the assets' life cycle. Amounts recorded in a business combination may change during the measurement period, which is a period not to exceed one year from the date of acquisition, as additional information about conditions existing at the acquisition date becomes available.

Goodwill and Finite-Lived Acquired Intangible Assets

Goodwill represents the excess of the purchase price paid over the fair value of tangible and identifiable intangible net assets acquired in business combinations and is allocated to the respective reporting units based on relative synergies generated.

Our intangible assets primarily consist of intangible assets acquired as part of our acquisitions. These assets are amortized using the straight-line method over their estimated useful lives ranging from two to fifteen years reflecting the period in which the economic benefits of the assets are expected to be realized.

Impairment of Goodwill and Long-Lived Assets

Goodwill

We evaluate goodwill for impairment at least annually on November 30th or more frequently if indicators are present, an event occurs or changes in circumstances suggest an impairment may exist and that it would more likely than not reduce the fair value of a reporting unit below its carrying amount. The allocation of goodwill to the respective reporting unit is based on relative synergies generated as a result of an acquisition.

We perform an initial assessment of qualitative factors to determine whether the existence of events and circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. In

performing the qualitative assessment, we identify and consider the significance of relevant key factors, events, and circumstances that affect the fair value of our reporting units. These factors include external factors such as macroeconomic, industry, and market conditions, as well as entity-specific factors, such as our actual and planned financial performance. We also give consideration to the difference between the reporting unit fair value and carrying value as of the most recent date a fair value measurement was performed. If, after assessing the totality of relevant events and circumstances, we determine that it is more likely than not that the fair value of the reporting unit exceeds its carrying value and there is no indication of impairment, no further testing is performed; however, if we conclude otherwise, then we will perform the quantitative impairment test which compares the estimated fair value of the reporting unit to its carrying value, including goodwill. If the carrying amount of the reporting unit is in excess of its fair value, an impairment loss would be recorded in the Consolidated Statement of Operations.

Long-Lived Assets

We evaluate long-lived assets (including finite-lived intangible assets) for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. An asset or asset group is considered impaired if its carrying amount exceeds the future undiscounted net cash flows that the asset or asset group is expected to generate. Factors we consider important which could trigger an impairment review include significant negative industry or economic trends, significant loss of customers and changes in the competitive environment. If an asset or asset group is considered to be impaired, the impairment to be recognized is calculated as the amount by which the carrying amount of the asset or asset group exceeds its fair market value. Our estimates of future cash flows attributable to our long-lived assets require significant judgment based on our historical and anticipated results and are subject to many assumptions. The estimation of fair value utilizing a discounted cash flow approach includes numerous uncertainties which require our significant judgment when making assumptions of expected growth rates and the selection of discount rates, as well as assumptions regarding general economic and business conditions, and the structure that would yield the highest economic value, among other factors. Refer to *Note 5* "*Goodwill and Intangible Assets*" *of Notes to Consolidated Financial Statements* for details on intangible long-lived assets.

Development Costs for Internal Use Software

Internally developed software includes enterprise-level business software that we customize to meet our specific operational needs. Such capitalized costs include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related costs for employees, who are directly associated with the development of the applications. There were no significant internally developed software costs capitalized in 2022 or 2021.

Development Costs for Software to be Marketed

The costs to develop software that is marketed externally have not been capitalized as we believe our current software development process is essentially completed concurrent with the establishment of technological feasibility. As such, all related software development costs are expensed as incurred and included in research and development expense in our Consolidated Statement of Operations.

Product Warranty

We offer assurance warranties on our products which provide the customer assurance that the product will function as the parties intended because it complies with agreed-upon specifications; therefore, warranties are not treated as a separate revenue performance obligation and are accounted for as guarantees under GAAP.

Clear Aligner

We warrant our Invisalign products against material defects until the treatment plan is complete except in the case of retainers, which are warranted up to three months from expected first use. We accrue for warranty costs, which are primarily based on historical experience as to product failures as well as current information on replacement costs.

Systems and Services

We warrant our intraoral scanners for a period of one year, which includes materials and labor. We accrue for these warranty costs based on average historical repair costs. An extended warranty may be purchased for additional fees. We warrant our CAD/CAM software for a one year period to perform in accordance with agreed product specifications. As we have not historically incurred any material warranty costs, we do not accrue for these software warranties.

Warranty costs are recorded in cost of net revenues upon shipment of products. We regularly review our warranty liability and update these balances based on historical warranty cost trends. Actual warranty costs incurred have not materially differed from those accrued; however future actual warranty costs could differ from the estimated amounts.

Revenue Recognition

Our revenues are derived primarily from the sale of aligners, scanners, and services from our Clear Aligner and Systems and Services segments. We enter into sales contracts that may consist of multiple distinct performance obligations where certain performance obligations of the sales contract are not delivered in one reporting period. We measure and allocate revenues according to ASC 606-10, "*Revenues from Contracts with Customers*."

We identify a performance obligation as distinct if both of the following criteria are met: the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. Determining the standalone selling price ("SSP") in order to allocate consideration from the contract to the individual performance obligations is the result of various factors, such as changing trends and market conditions, historical prices, costs, and gross margins. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenues recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on our financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

Clear Aligner

We enter into contracts ("treatment plan(s)") that involve multiple future performance obligations. Invisalign Comprehensive, Invisalign First, Invisalign Moderate, Invisalign Go, Invisalign Go Plus, and Lite and Express Packages include optional additional aligners at no charge for a certain period of time ranging from six months to five years after initial shipment.

Our treatment plans comprise the following performance obligations that also represent distinct deliverables: initial aligners, the option of additional aligners, case refinement, and replacement aligners. We take the practical expedient to consider shipping and handling costs as activities to fulfill the performance obligation. Where processing fees are charged, the consideration received from the fees are included in the total consideration. We allocate revenues for each treatment plan based on each unit's standalone selling price. Management considers a variety of factors such as same or similar product historical sales, costs, and gross margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. In addition to historical data, we take into consideration changing trends and market conditions. For treatment plans with multiple future options, we also consider usage rates, which is the number of times a customer is expected to order additional aligners. Our process for estimating usage rates requires significant judgment and evaluation of inputs, including historical usage data by region, country and channel. We recognize the revenues upon shipment, as the customers obtain physical possession and we have enforceable rights to payment. As we collect most consideration upfront, we consider whether a significant financing component exists; however, as the delivery of the performance obligations are at the customer's discretion, we conclude that no significant financing component exists.

Systems and Services

We sell intraoral scanners and CAD/CAM services through both our direct sales force and distribution partners. The intraoral scanner sales price includes one year of warranty and unlimited scanning services. The customer may also select, for additional fees, extended warranty and unlimited scanning services for periods beyond the initial year. When intraoral scanners are sold with an unlimited scanning service agreement and/or extended warranty, we allocate revenues based on the respective SSP of the scanner and the subscription service. We estimate the SSP of each element, taking into account factors such as same or similar historical prices and discounting strategies. Revenues are then recognized over time as the monthly services are rendered and upon shipment of the scanner, as that is when we deem the customer to have obtained control. We also have a rental program, where scanners are leased to customers. The contracts for the program are treated as operating leases, and the revenue is recognized ratably over the lease term.

CAD/CAM services, where sold separately, include the initial software license and maintenance and support. We allocate revenues based upon the respective SSPs of the software license and the maintenance and support. We estimate the SSP of each element using data such as historical prices. Revenues related to the software license are recognized upfront and revenues related to the maintenance and support are recognized over time. For both scanner and service sales, most consideration is

collected upfront and in cases where there are payment plans, consideration is collected within one year and, therefore, there are no significant financing components.

Volume Discounts

In certain situations, we offer promotions in which the discount will increase depending upon the volume purchased over time. We concluded that in these situations, the promotions can represent either variable consideration or options, depending upon the specifics of the promotion. In the event the promotion contains an option, the option is considered a material right and, therefore, included in the accounting for the initial arrangement. We estimate the average anticipated discount over the lifetime of the promotion or contract, and apply that discount to each unit as it is sold. On a quarterly basis, we review our estimates and, if needed, updates are made and changes are applied prospectively.

Accrued Sales Return Reserve

We provide a reserve for sales returns based on historical sales returns as a percentage of revenues.

Costs to Obtain a Contract

We offer a variety of commission plans to our salesforce; each plan has multiple components. To match the costs to obtain a contract to the associated revenues, we evaluate the individual components and capitalize the eligible components, recognizing the costs over the treatment period. The costs to obtain contracts were $27.4 million and $31.1 million as of December 31, 2022 and 2021, respectively, and are included in other assets in our Consolidated Balance Sheets. We recognized amortization on our costs to obtain a contract of $20.8 million, $17.0 million, and $10.1 million during the year ended December 31, 2022, 2021, and 2020, respectively, which is included in selling, general and administrative expenses in our Consolidated Statements of Operations.

Unfulfilled Performance Obligations for Clear Aligners and Scanners

Our unfulfilled performance obligations, including deferred revenues and backlog, as of December 31, 2022 and the estimated revenues expected to be recognized in the future related to these performance obligations are $1,515.4 million. This includes performance obligations from the Clear Aligner segment, primarily the shipment of additional aligners, which are fulfilled over six months to five years. This also includes the performance obligations from the Systems and Services segment, primarily services and support, which are fulfilled over one to five years, and contracted deliveries of additional scanners. The estimate includes both product and service unfulfilled performance obligations and the time range reflects our best estimate of when we will transfer control to the customer and may change based on customer usage patterns, timing of shipments, readiness of customers' facilities for installation, and manufacturing availability.

Contract Balances

The timing of revenue recognition results in deferred revenues being recognized on our Consolidated Balance Sheet. For both aligners and scanners, we usually collect the total consideration owed prior to all performance obligations being performed with payment terms generally varying from net 30 to net 180 days. Contract liabilities are recorded as deferred revenue balances, which are generated based upon timing of invoices and recognition patterns, not payments. If the revenue recognition exceeds the billing, the exceeded amount is considered unbilled receivable and a contract asset. Conversely, if the billing occurs prior to the revenue recognition, the amount is considered deferred revenue and a contract liability.

Shipping and Handling Costs

Shipping and handling charges to customers as well as processing fees are included in net revenues, and the associated costs incurred are recorded in cost of net revenues.

Legal Proceedings and Litigations

We are involved in legal proceedings on an ongoing basis. If we believe that a loss arising from such matters is probable and can be reasonably estimated, we accrue the estimated loss in our consolidated financial statements. If only a range of estimated losses can be determined, we accrue an amount within the range that, in our judgment, reflects the most likely outcome; if none of the estimates within that range is a better estimate than any other amount, we accrue the low end of the range.

Research and Development

Research and development costs are expensed as incurred and includes the costs associated with the research and development of new products and enhancements to existing products. These costs primarily include personnel-related costs, including payroll and stock-based compensation, equipment, material and maintenance costs, outside consulting expenses, depreciation and amortization expense and allocations of corporate overhead expenses including facilities and information technology ("IT").

Advertising Costs

The cost of advertising and media is expensed as incurred. For the year ended December 31, 2022, 2021 and 2020, we incurred advertising costs of $222.0 million, $325.6 million and $161.0 million, respectively.

Stock-Based Compensation

We recognize stock-based compensation cost for shares expected to vest on a straight-line basis over the requisite service period of the award, net of estimated forfeitures. We use the Black-Scholes option pricing model to determine the fair value of employee stock purchase plan shares. We use a Monte Carlo simulation model to estimate the fair value of market-performance based restricted stock units which requires the input of assumptions, including expected term, stock price volatility and the risk-free rate of return. For restricted stock units which vest based on performance conditions, we use the stock price on the grant date to estimate the fair value and stock-based compensation cost is recorded based on expected attainment of performance targets. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenues and expenses for tax and financial statement purposes.

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the applicable tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities which are included in our Consolidated Balance Sheets.

We account for uncertainty in income taxes pursuant to authoritative guidance based on a two-step approach to recognize and measure uncertain tax positions taken or expected to be taken in a tax return. The first step is to determine if the weight of available evidence indicates that it is more likely than not that the tax position will be sustained on audit based on its technical merits, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. We adjust reserves for our uncertain tax positions due to changing facts and circumstances, such as the closing of a tax audit or refinement of estimates due to new information. To the extent that the final outcome of these matters is different than the amounts recorded, such differences will impact our tax provision in our Consolidated Statement of Operations in the period in which such determination is made.

We assess the likelihood that we will be able to realize our deferred tax assets. Should there be a change in our ability to realize our deferred tax assets, our tax provision would increase in the period in which we determine that it is more likely than not that we cannot realize our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is more likely than not that we will not realize our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be realizable.

During fiscal 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss subsidiary, which resulted in the recognition of deferred tax assets and related tax benefits. Refer to *Note 12 "Income Taxes" of Notes to Consolidated Financial Statements* for more information. The establishment of deferred tax assets from the intra-entity transfer of intangible assets required us to make significant estimates and assumptions to determine the fair value of intellectual property rights transferred which include, but are not limited to, our expectations of growth rates in revenue, margins, future cash flows, and discount rates. The accuracy of these estimates could be affected by unforeseen events or actual

results, and the sustainability of our future tax benefits is dependent upon the acceptance of these valuation estimates and assumptions by the taxing authorities.

The U.S. Tax Cuts and Jobs Act includes provisions for certain foreign-sourced earnings referred to as Global Intangible Low-Taxed Income ("GILTI") which imposes a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. We have made the election to record GILTI tax using the period cost method.

Common Stock Repurchase

We repurchase our own common stock from time to time under stock repurchase programs approved by our Board of Directors. We account for these repurchases under the accounting guidance for equity where we allocate the total repurchase value that is in excess over par value between additional paid-in capital and retained earnings. All shares repurchased are retired.

Recent Accounting Pronouncements

(i) New Accounting Updates Recently Adopted

In October 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2021-08, "*Business Combinations (Topic 805) Accounting for Contract Assets and Contract Liabilities from Contracts with Customers,*" which requires contract assets and contract liabilities acquired in a business combination to be recognized and measured in accordance with ASC 606, *Revenue from Contracts with Customers* as if the acquirer had originated the contracts. The updated guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2022 on a prospective basis and early adoption is permitted. We early adopted this standard during 2022 which did not have a material impact on our consolidated financial statements and related disclosures.

(ii) Recent Accounting Pronouncements Not Yet Effective

We continue to monitor new accounting pronouncements issued by the FASB and do not believe any of the recently issued accounting pronouncements will have a material impact on our consolidated financial statements or related disclosures.

Note 2. Financial Instruments

Cash, Cash Equivalents and Marketable Securities

The following tables summarize our cash and cash equivalents, and marketable securities on our Consolidated Balance Sheet as of December 31, 2022 and 2021 (in thousands):

					Reported as:		
December 31, 2022	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**	**Cash and Cash Equivalents**	**Marketable securities, short-term**	**Marketable securities, long-term**
Cash	$ 712,921	$ —	$ —	$ 712,921	$ 712,921	$ —	$ —
Money market funds	229,129	—	—	229,129	229,129	—	—
Corporate bonds	69,390	—	(2,915)	66,475	—	36,510	29,965
U.S. government treasury bonds	20,559	—	(549)	20,010	—	15,404	4,606
Asset-backed securities	4,514	1	(37)	4,478	—	2,909	1,569
Municipal bonds	3,447	—	(61)	3,386	—	2,711	675
U.S. government agency bonds	5,231	1	(69)	5,163	—	—	5,163
Total	$1,045,191	$ 2	$ (3,631)	$1,041,562	$ 942,050	$ 57,534	$ 41,978

December 31, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Reported as: Cash and Cash Equivalents	Marketable securities, short-term	Marketable securities, long-term
Cash	$ 754,802	$ —	$ —	$ 754,802	$ 754,802	$ —	$ —
Money market funds	343,012	—	(2)	343,010	343,010	—	—
Corporate bonds	115,507	9	(398)	115,118	1,042	35,065	79,011
U.S. government treasury bonds	42,976	—	(48)	42,928	—	22,251	20,677
Asset-backed securities	32,031	—	(40)	31,991	—	10,999	20,992
Municipal bonds	7,628	—	(15)	7,613	516	3,657	3,440
U.S. government agency bonds	1,201	—	(1)	1,200	—	—	1,200
Total	$1,297,157	$ 9	$ (504)	$1,296,662	$1,099,370	$ 71,972	$ 125,320

The following table summarizes the fair value of our available-for-sale marketable securities classified by contractual maturity as of December 31, 2022 and 2021 (in thousands):

	December 31,	
	2022	2021
Due in 1 year or less	$ 51,037	$ 59,737
Due in 1 year through 5 years	48,475	139,113
Total	$ 99,512	$ 198,850

The securities that we invest in are generally deemed to be low risk based on their credit ratings from the major rating agencies. The longer the duration of these securities, the more susceptible they are to changes in market interest rates and bond yields. As interest rates increase, those securities purchased at a lower yield show a mark-to-market unrealized loss. Our unrealized losses as of December 31, 2022 and 2021 are primarily due to changes in interest rates and credit spreads.

The following table summarizes the gross unrealized losses as of December 31, 2022, aggregated by investment category and length of time that individual securities have been in a continuous loss position (in thousands):

	As of December 31, 2022					
	Less than 12 months		12 Months of Greater		Total	
December 31, 2022	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ 10,639	$ (440)	$ 54,634	$ (2,475)	$ 65,273	$ (2,915)
U.S. government treasury bonds	5,262	(177)	14,748	(372)	20,010	(549)
Asset-backed securities	2,636	(17)	1,275	(20)	3,911	(37)
Municipal bonds	—	—	2,412	(61)	2,412	(61)
U.S. government agency bonds	3,017	(5)	1,136	(64)	4,153	(69)
Total	$ 21,554	$ (639)	$ 74,205	$ (2,992)	$ 95,759	$ (3,631)

As of December 31, 2021, all gross unrealized losses had been in an unrealized loss position for less than 12 months.

Investment in SmileDirectClub, LLC ("SDC")

After tendering of our SDC equity interest in 2019, on July 3, 2019, we filed a demand for arbitration regarding SDC's calculation of the "capital account" balance. On March 12, 2021, the arbitrator ruled in our favor and against SDC and issued an award of $43.4 million along with interest. The gain of $43.4 million was recognized as a part of our other income (expense), net in our Consolidated Statement of Operation during the year ended December 31, 2021.

Fair Value Measurements

The following tables summarize our financial assets measured at fair value as of December 31, 2022 and 2021 (in thousands):

Description	Balance as of December 31, 2022	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 229,129	$ 229,129	$ —
Short-term investments:			
U.S. government treasury bonds	15,404	15,404	—
Corporate bonds	36,510	—	36,510
Municipal bonds	2,711	—	2,711
Asset-backed securities	2,909	—	2,909
Long-term investments:			
U.S. government treasury bonds	4,606	4,606	—
Corporate bonds	29,965	—	29,965
Municipal bonds	675	—	675
U.S. government agency bonds	5,163	—	5,163
Asset-backed securities	1,569	—	1,569
	$ 328,641	$ 249,139	$ 79,502

Description	Balance as of December 31, 2021	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 343,010	$ 343,010	$ —
Corporate bonds	1,042	—	1,042
Municipal bonds	516	—	516
Short-term investments:			
U.S. government treasury bonds	22,251	22,251	—
Corporate bonds	35,065	—	35,065
Municipal bonds	3,657	—	3,657
Asset-backed securities	10,999	—	10,999
Long-term investments:			
U.S. government treasury bonds	20,677	20,677	—
Corporate bonds	79,011	—	79,011
Municipal bonds	3,440	—	3,440
U.S. government agency bonds	1,200	—	1,200
Asset-backed securities	20,992	—	20,992
Prepaid expenses and other current assets:			
Israeli funds	3,841	—	3,841
	$ 545,701	$ 385,938	$ 159,763

Derivatives Not Designated as Hedging Instruments

Recurring foreign currency forward contracts

We enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on certain trade and intercompany receivables and payables. These forward contracts are classified within Level 2 of the fair value hierarchy. As a result of the settlement of foreign currency forward contracts, the net gain recognized during the year ended December 31, 2022 was not material and we recognized a net gain of $18.8 million and a net loss of $22.1 million, during the year ended December 31, 2021 and 2020, respectively. As of December 31, 2022 and 2021, the fair value of foreign exchange forward contracts outstanding was not material.

The following tables presents the gross notional value of all our foreign exchange forward contracts outstanding as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€186,900	$ 200,010
Polish Zloty	PLN365,988	83,307
Canadian Dollar	C$109,000	80,514
Chinese Yuan	¥471,000	68,223
British Pound	£41,200	49,677
Japanese Yen	¥6,200,000	47,196
Israeli Shekel	ILS110,030	31,383
Swiss Franc	CHF25,000	27,165
Brazilian Real	R$141,200	26,839
Mexican Peso	M$230,000	11,746
New Zealand Dollar	NZ$6,000	3,806
Australian Dollar	A$4,000	2,721
Czech Koruna	Kč56,000	2,469
New Taiwan Dollar	NT$60,000	1,959
		$ 637,015

	December 31, 2021	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€165,110	$ 186,358
Canadian Dollar	C$99,800	78,018
Chinese Yuan	¥494,500	77,358
Polish Zloty	PLN219,800	54,014
Brazilian Real	R$286,500	50,894
Japanese Yen	¥5,548,700	48,206
British Pound	£34,740	46,881
Israeli Shekel	ILS54,110	17,416
Mexican Peso	M$311,500	15,133
Swiss Franc	CHF9,950	10,883
Australian Dollar	A$6,900	5,009
		$ 590,170

Other foreign currency forward contract

Prior to the closing of the exocad acquisition on April 1, 2020, we entered into a Euro foreign currency forward contract with a notional contract amount of €376.0 million. Relating to this forward contract, in 2020, we recognized a loss of $10.2 million within other income (expense), net in our Consolidated Statement of Operations.

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 172,758	$ 123,234
Work in progress	96,558	51,706
Finished goods	69,436	55,290
Total inventories	$ 338,752	$ 230,230

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2022	2021
Value added tax receivables	$ 140,484	$ 93,610
Prepaid expenses	69,124	70,218
Other current assets	16,762	31,477
Total prepaid expenses and other current assets	$ 226,370	$ 195,305

Property, plant and equipment consist of the following (in thousands):

		December 31,	
	Generally Used Estimated Useful Life	2022	2021
Clinical and manufacturing equipment	Up to 10 years	$ 583,776	$ 452,876
Building	20 years	466,003	310,344
Leasehold improvements	Lease term [1]	64,238	61,289
Computer software and hardware	3 years	120,544	117,986
Land	—	58,885	58,869
Furniture, fixtures and other	2-5 years	102,933	71,977
Construction in progress	—	285,202	367,686
Total		1,681,581	1,441,027
Less: Accumulated depreciation and impairment charges		(449,726)	(359,101)
Total property, plant and equipment, net		$ 1,231,855	$ 1,081,926

[1] Shorter of the remaining lease term or the estimated useful lives of the assets

Depreciation was $109.8 million, $92.1 million and $80.1 million for the year ended December 31, 2022, 2021 and 2020, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2022	2021
Accrued payroll and benefits	$ 149,508	$ 288,355
Accrued income taxes	74,323	33,838
Accrued expenses	64,341	67,169
Accrued sales and marketing expenses	36,407	41,387
Current operating lease liabilities	26,574	22,719
Accrued property, plant and equipment	19,922	46,561
Other accrued liabilities	83,299	107,286
Total accrued liabilities	$ 454,374	$ 607,315

Accrued warranty as of December 31, 2022 and 2021, which is included in the "Other accrued liabilities" category of the accrued liabilities table above, consists of the following activity (in thousands):

Accrued warranty as of December 31, 2020	$	12,615
Charged to cost of net revenues		18,213
Actual warranty expenditures		(14,659)
Accrued warranty as of December 31, 2021		16,169
Charged to cost of net revenues		16,429
Actual warranty expenditures		(14,725)
Accrued warranty as of December 31, 2022	$	17,873

Deferred revenues consist of the following (in thousands):

	December 31,	
	2022	2021
Deferred revenues - current	$ 1,343,643	$ 1,152,870
Deferred revenues - long-term [1]	160,662	136,684

[1] Included in Other long-term liabilities within our Consolidated Balance Sheet

During the year ended December 31, 2022 and 2021, we recognized $3,734.6 million and $3,952.6 million of net revenues, respectively, of which $635.3 million and $481.1 million was included in the deferred revenues balance at December 31, 2021 and December 31, 2020, respectively.

Note 4. Leases

Lessee Information

We have operating leases for our digital treatment planning and office facilities, retail spaces, vehicles and office equipment. The components of lease expenses consist of following (in thousands):

	Year Ended December 31,		
Lease Cost	**2022**	**2021**	**2020**
Operating lease cost [1]	$ 37,919	$ 33,241	$ 27,825
Variable lease cost [2]	22,084	11,134	1,429
Total lease cost	$ 60,003	$ 44,375	$ 29,254

[1] Includes expense associated with short term leases of less than 12 months which is not material

[2] Includes payments related to agreements with embedded leases that are not otherwise reflected on the balance sheet. These costs are primarily associated with our manufacturing supply arrangements and fluctuate based on factory output and material price changes.

The following table provides a summary of our operating lease terms and discount rates:

	December 31,	
Remaining Lease Term and Discount Rate	**2022**	**2021**
Weighted average remaining lease term (in years)	7.2	7.8
Weighted average discount rate	3.5 %	3.2 %

As of December 31, 2022, the future payments related to our operating lease liabilities are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases
2023	$ 30,596
2024	24,606
2025	19,480
2026	16,511
2027	13,363
Thereafter	39,449
Total lease payments	144,005
Less: Imputed interest	(17,097)
Total lease liabilities	$ 126,908

As of December 31, 2022, we had additional leases that have not yet commenced with future lease payments of $14.3 million. These leases will commence during 2023 with non-cancelable lease terms of three to six years.

Lessor Information

We lease iTero intraoral scanners to customers which are classified as operating leases. Our portfolio of leased iTero scanners included in Property, plant and equipment, net are as follows:

	December 31,	
	2022	2021
Scanners under operating leases, gross	$ 22,914	$ 10,927
Less: accumulated depreciation	(3,919)	(785)
Scanners under operating leases, net	$ 18,995	$ 10,142

As of December 31, 2022, the future lease payments due to us are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases
2023	$ 15,714
2024	13,967
2025	6,202
Total lease payments	$ 35,883

For the year ended December 31, 2022, operating lease income was $12.3 million and for the years ended December 31, 2021 and 2020, operating lease income was not material.

Note 5. Goodwill and Intangible Assets

During the year ended December 31, 2022, we completed an immaterial business combination which increased goodwill and existing technology intangible assets.

Goodwill

The change in the carrying value of goodwill for the year ended December 31, 2022 and 2021, categorized by reportable segments, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
Balance as of December 31, 2020	$ 112,691	$ 332,126	$ 444,817
Additions from acquisition	3,646	—	3,646
Foreign currency translation adjustments	(4,129)	(25,787)	(29,916)
Balance as of December 31, 2021	112,208	306,339	418,547
Additions from acquisition	—	8,729	8,729
Foreign currency translation adjustments	(2,728)	(16,997)	(19,725)
Balance as of December 31, 2022	$ 109,480	$ 298,071	$ 407,551

We completed our annual goodwill impairment assessments in 2022 and 2021 and determined there were no impairments.

Intangible Long-Lived Assets

Acquired intangible long-lived assets were as follows, excluding intangibles that were fully amortized (in thousands):

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2022	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2022
Existing technology	10	$ 112,051	$ (33,537)	$ (4,328)	$ 74,186
Customer relationships	10	21,500	(5,913)	—	15,587
Trademarks and tradenames	10	17,200	(6,442)	(4,122)	6,636
Patents	8	6,511	(5,288)	—	1,223
		$ 157,262	$ (51,180)	$ (8,450)	97,632
Foreign currency translation adjustments					(1,912)
Total intangible assets, net [1]					$ 95,720

[1] Also includes $33.5 million of fully amortized intangible assets related to customer relationships.

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2021	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2021
Existing technology	10	$ 104,531	$ (22,495)	$ (4,328)	$ 77,708
Customer relationships	11	55,000	(25,891)	(10,751)	18,358
Trademarks and tradenames	10	17,200	(4,547)	(4,179)	8,474
Patents	8	6,511	(4,495)	—	2,016
		$ 183,242	$ (57,428)	$ (19,258)	106,556
Foreign currency translation adjustments					3,153
Total intangible assets, net					$ 109,709

There were no triggering events in 2022 or 2021 that would cause impairments of our intangible long-lived assets.

The total estimated annual future amortization expense for these acquired intangible assets as of December 31, 2022 is as follows (in thousands):

Fiscal Year	Amortization
2023	$ 16,501
2024	15,335
2025	14,959
2026	14,353
2027	11,992
Thereafter	24,492
Total	$ 97,632

Amortization expense was $16.0 million, $16.6 million and $13.4 million for the year ended December 31, 2022, 2021 and 2020, respectively.

Note 6. Credit Facility

We have a credit facility that provides for a $300.0 million unsecured revolving line of credit, along with a $50.0 million letter of credit. On December 23, 2022, we amended certain provisions in our credit facility which included extending the maturity date on the facility to December 23, 2027 and replacing the interest rate from the existing LIBOR with SOFR ("2022 Credit Facility"). The 2022 Credit Facility requires us to comply with specific financial conditions and performance requirements. Loans under the 2022 Credit Facility bear interest, at our option, at either a rate based on the SOFR for the applicable interest period or a base rate, in each case plus a margin. As of December 31, 2022, we had no outstanding borrowings under the 2022 Credit Facility and were in compliance with the conditions and performance requirements in all material respects.

Note 7. Legal Proceedings

2019 Shareholder Derivative Lawsuit

In January 2019, three derivative lawsuits were filed in the U.S. District Court for the Northern District of California which were later consolidated, purportedly on our behalf, naming as defendants the then current members of our Board of Directors along with certain of our executive officers. The complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment. The complaints seek unspecified monetary damages on our behalf, which is named solely as a nominal defendant against whom no recovery is sought, as well as disgorgement and the costs and expenses associated with the litigation, including attorneys' fees. The consolidated action is currently stayed. Defendants have not yet responded to the complaints.

On April 12, 2019, a derivative lawsuit was also filed in California Superior Court for Santa Clara County, purportedly on our behalf, naming as defendants the members of our Board of Directors along with certain of our executive officers. The allegations in the complaint are similar to those in the derivative suits described above. The matter is currently stayed. Defendants have not yet responded to the complaint.

We believe these claims are without merit. We are currently unable to predict the outcome of these lawsuits and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

2020 Securities Class Action Lawsuit

On March 2, 2020, a class action lawsuit against us and two of our executive officers was filed in the U.S. District Court for the Southern District of New York (later transferred to the U.S. District Court for the Northern District of California) on behalf of a purported class of purchasers of our common stock. The complaint alleged claims under the federal securities laws and sought monetary damages in an unspecified amount and costs and expenses incurred in the litigation. The lead plaintiff filed an amended complaint on August 4, 2020 against us and three of our executive officers alleging similar claims as in the initial complaint on behalf of a purported class of purchasers of our common stock from April 25, 2019 to July 24, 2019. On March 29, 2021, defendants' motion to dismiss the amended complaint was granted with leave for the lead plaintiff to file a further amended complaint. On April 22, 2021, lead plaintiff filed a notice stating it would not file a further amended complaint. On April 23, 2021, the Court dismissed the action with prejudice and judgment was entered. Lead plaintiff filed a notice of appeal on April 28, 2021 and filed its opening appeal brief with the United States Court of Appeals for the Ninth

Circuit on September 1, 2021. The defendants-appellees filed their answering brief on November 22, 2021. The lead plaintiff-appellant's reply brief was filed on January 12, 2022. Oral argument was held on March 10, 2022. On July 8, 2022, a panel of the Ninth Circuit affirmed the district court order dismissing the complaint. On July 21, 2022, plaintiff-appellant filed a petition for rehearing or hearing en banc, which the court denied on August 15, 2022. On November 14, 2022, the deadline for plaintiff-appellant to file a petition for writ of certiorari to the United States Supreme Court passed without plaintiff-appellant filing a petition, finally resolving this matter in our favor.

Antitrust Class Actions

On June 5, 2020, a dental practice named Simon and Simon, PC doing business as City Smiles brought an antitrust action in the U.S. District Court for the Northern District of California on behalf of itself and a putative class of similarly situated practices seeking monetary damages and injunctive relief relating to our alleged market activities in alleged clear aligner and intraoral scanner markets. Plaintiff filed an amended complaint and added VIP Dental Spas as a plaintiff on August 14, 2020. A jury trial is scheduled to begin in this matter on June 29, 2024. We believe the plaintiffs' claims are without merit and we intend to vigorously defend ourselves.

On May 3, 2021, an individual named Misty Snow brought an antitrust action in the U.S. District Court for the Northern District of California on behalf of herself and a putative class of similarly situated individuals seeking monetary damages and injunctive relief relating to our alleged market activities in alleged clear aligner and intraoral scanner markets. Plaintiff filed an amended complaint on July 30, 2021 adding new plaintiffs and various state law claims. Plaintiffs filed a second amended complaint on October 21, 2021. On March 2, 2022, Plaintiffs filed a third amended complaint. On October 3, 2022, Plaintiffs filed a fourth amended complaint. A jury trial is scheduled to begin in this matter on June 29, 2024 for issues related to Section 2 allegations. A jury trial is scheduled to begin in this matter on September 30, 2024 for issues related to Section 1 allegations. We believe the plaintiffs' claims are without merit and we intend to vigorously defend ourselves.

We are currently unable to predict the outcome of these lawsuits and therefore we cannot determine the likelihood of loss, if any, nor estimate a range of possible loss.

SDC Dispute

On August 27, 2020, we initiated a confidential arbitration proceeding against SmileDirectClub LLC ("SDC") before the American Arbitration Association in San Jose, California. This arbitration relates to the Strategic Supply Agreement ("Supply Agreement") entered into between the parties in 2016. The complaint alleges that SDC breached the Supply Agreement's terms, causing damages to us in an amount to be determined. On January 19, 2021, SDC filed a counterclaim alleging that we breached the Supply Agreement. On May 3, 2022, SDC filed an additional counterclaim alleging that we breached the Supply Agreement. We deny SDC's allegations in the counterclaims and we intend to vigorously defend ourselves against them. The arbitration hearing on our claims and SDC's first counterclaim was held on July 18-27, 2022 in Chicago, Illinois.

On October 27, 2022, the arbitrator issued an interim award on our claims and SDC's first counterclaim finding that SDC breached the Supply Agreement, we did not breach the Supply Agreement, and SDC caused harm to us. Based on these findings, the arbitrator awarded us an interim award that, when confirmed, may be material to our results in the quarter reported.

On December 2, 2022, SDC filed a motion to re-open the arbitrator's interim award in Align's favor. We anticipate recognizing the amount ultimately realizable following confirmation of the final award.

The arbitration hearing on SDC's second counterclaim was held on February 21-23, 2023 in Chicago, Illinois. We are currently unable to predict the outcome of SDC's second counterclaim and therefore cannot determine the likelihood of loss or success nor estimate a range of possible loss or success, if any.

In addition to the above, in the ordinary course of our operations, we are involved in a variety of claims, suits, investigations, and proceedings, including actions with respect to intellectual property claims, patent infringement claims, government investigations, labor and employment claims, breach of contract claims, tax, and other matters. Regardless of the outcome, these proceedings can have an adverse impact on us because of defense costs, diversion of management resources, and other factors. Although the results of complex legal proceedings are difficult to predict and our view of these matters may change in the future as litigation and events related thereto unfold; we currently do not believe that these matters, individually or in the aggregate, will materially affect our financial position, results of operations or cash flows.

Note 8. Commitments and Contingencies

Unconditional Purchase Obligations

On October 30, 2020, we entered into a subscription agreement with a software company to renew our license for a total consideration of $95.2 million. As of December 31, 2022, we had a remaining commitment of $23.8 million which is expected to be paid through 2024.

On December 6, 2020, we entered into a supply agreement for certain components used for our manufacturing operations. As of December 31, 2022, we had purchase commitments of $85.8 million which is expected to be paid through 2025.

On June 24, 2021, we entered into an amended purchase agreement with an existing single source supplier which requires us to purchase aligner material for a minimum amount of approximately $348.0 million from 2023 through 2026.

On March 11, 2022, we entered into an amended promotional rights agreement with a third-party which includes advertising and media coverage. As of December 31, 2022, we had a remaining commitment of $60.0 million which is expected to be paid through 2026.

On December 9, 2022, we entered into a cloud services agreement to support our production operations and research and development efforts for clinical applications which requires us to make minimum purchases totaling $145.0 million from 2023 through 2027.

Off-Balance Sheet Arrangements

As of December 31, 2022, we had no material off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources other than certain items disclosed in the Unconditional Purchase Obligations section above.

Indemnification Provisions

In the normal course of business to facilitate transactions in our services and products, we indemnify certain parties: customers, vendors, lessors, and other parties with respect to certain matters, including, but not limited to, services to be provided by us and intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with our directors and our executive officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. Several of these agreements limit the time within which an indemnification claim can be made and the amount of the claim.

It is not possible to make a reasonable estimate of the maximum potential amount under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of December 31, 2022, we did not have any material indemnification claims that were probable or reasonably possible.

Note 9. Stockholders' Equity

Common Stock

The holders of common stock are entitled to receive dividends whenever funds are legally available and when and if declared by the Board of Directors. We have never declared or paid dividends on our common stock.

Stock-Based Compensation Plans

Our 2005 Incentive Plan, as amended, provides for the granting of incentive stock options, non-statutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, non-employee directors and consultants. Shares granted on or after May 16, 2013 as an award of restricted stock, restricted stock units, performance shares or performance units ("full value awards") are counted against the authorized share reserve as one and nine-tenths (1 9/10) shares for every one (1) share subject to the award, and any shares canceled that were counted as one and nine-tenths against the plan reserve will be returned at the same ratio.

As of December 31, 2022, the 2005 Incentive Plan, as amended, has a total reserve of 27,783,379 shares for issuance of which 3,760,672 shares are available for issuance. We issue new shares from our pool of authorized but unissued shares to satisfy the exercise and vesting obligations of our stock-based compensation plans.

Summary of Stock-Based Compensation Expense

The stock-based compensation related to our stock-based awards and employee stock purchase plan for the year ended December 31, 2022, 2021 and 2020 is as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of net revenues	$ 6,438	$ 5,633	$ 4,719
Selling, general and administrative	103,134	90,659	78,500
Research and development	23,795	18,044	15,208
Total stock-based compensation	$ 133,367	$ 114,336	$ 98,427

The income tax benefit related to stock-based compensation was $14.9 million, $13.8 million and $11.9 million for the year ended December 31, 2022, 2021 and 2020, respectively.

Restricted Stock Units ("RSUs")

The fair value of RSUs is based on our closing stock price on the date of grant. RSUs granted generally vest over a period of four years. A summary for the year ended December 31, 2022 is as follows:

	Number of Shares Underlying RSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Unvested as of December 31, 2021	492	$ 369.17		
Granted	248	469.12		
Vested and released	(200)	333.76		
Forfeited	(51)	437.05		
Unvested as of December 31, 2022	489	$ 427.23	1.2	$ 103,138

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by multiplying our closing stock price on the last trading day of 2022 by the number of unvested RSUs) that would have been received by the unit holders had all RSUs been vested and released as of the last trading day of 2022. This amount will fluctuate based on the fair market value of our stock. During 2022, of the 199,832 shares vested and released, 59,115 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 140,717 shares.

The total fair value of RSUs vested as of their respective vesting dates during 2022, 2021 and 2020 was $93.7 million, $158.8 million and $89.6 million, respectively. The weighted average grant date fair value of RSUs granted during 2022, 2021 and 2020 was $469.12, $600.10 and $267.24, respectively. As of December 31, 2022, we expect to recognize $133.4 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 2.2 years.

Market-Performance Based Restricted Stock Units ("MSUs")

We grant MSUs to members of senior management. Each MSU represents the right to one share of our common stock. The actual number of MSUs which will be eligible to vest will be based on the performance of our stock price relative to the performance of a stock market index over the vesting period. MSUs vest over a period of three years and the maximum number eligible to vest in the future is 250% of the MSUs initially granted.

The following table summarizes the MSU performance activity for the year ended December 31, 2022:

	Number of Shares Underlying MSUs (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Unvested as of December 31, 2021	174	$ 551.57		
Granted [1]	101	607.96		
Vested and released	(128)	396.10		
Forfeited	(3)	744.39		
Unvested as of December 31, 2022	144	$ 725.73	1.0	$ 30,384

[1] Includes MSUs vested during the period above 100% of the grant as actual shares released is based on our stock performance over the vesting period

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by multiplying our closing stock price on the last trading day of 2022 by the number of unvested MSUs) that would have been received by the unit holders had all MSUs been vested and released as of the last trading day of 2022. This amount will fluctuate based on the fair market value of our stock. During 2022, of the 128,259 shares vested and released, 49,524 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 78,735 shares.

The total fair value of MSUs vested as of their respective vesting dates during 2022, 2021 and 2020 was $64.0 million, $135.6 million and $47.1 million, respectively. As of December 31, 2022, we expect to recognize $40.1 million of total unamortized compensation costs, net of estimated forfeitures, related to MSUs over a weighted average period of 1.0 year.

The fair value of MSUs is estimated at the grant date using a Monte Carlo simulation that includes factors for market conditions. The weighted average assumptions used in the Monte Carlo simulation were as follows:

	Year Ended December 31,		
	2022	2021	2020
Expected term (in years)	3.0	3.0	3.0
Expected volatility	53.8 %	56.3 %	44.4 %
Risk-free interest rate	1.7 %	0.2 %	1.4 %
Expected dividends	—	—	—
Weighted average fair value per share at grant date	$ 915.22	$ 1,102.09	$ 392.67

Restricted Stock Units with Performance Conditions ("PSUs")

In the fourth quarter of 2022, we granted PSUs to certain employees which are eligible to vest based on the achievement of project-based milestones over a term of 2.2 years. Total PSUs granted were 4,728 and the weighted average grant date fair value for the PSUs was $201.63.

Employee Stock Purchase Plan ("ESPP")

In May 2010, our stockholders approved the 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan") which consists of consecutive overlapping twenty-four month offering periods with four six-month purchase periods in each offering period. Employees purchase shares at 85% of the lower of the fair market value of the common stock at either the beginning of the offering period or the end of the purchase period. The 2010 Purchase Plan will continue until terminated by either the Board of Directors or its administrator. The 2010 Purchase Plan also allows for purchase rights to employees outside the U.S. and Canada with six-month offering periods and purchase periods. In May 2021, the 2010 Purchase Plan was amended and restated to increase the maximum number of shares available for purchase to 4,400,000 shares.

The following table summarizes the ESPP shares issued:

	Year Ended December 31,		
	2022	2021	2020
Number of shares issued (in thousands)	86	131	116
Weighted average price	$ 305.24	$ 195.44	$ 175.69

As of December 31, 2022, 2,108,898 shares remain available for future issuance.

The fair value of the option component of the 2010 Purchase Plan shares was estimated at the grant date using the Black-Scholes option pricing model with the following weighted average assumptions:

	Year Ended December 31,		
	2022	2021	2020
Expected term (in years)	1.5	1.1	1.0
Expected volatility	50.2 %	52.7 %	55.0 %
Risk-free interest rate	1.8 %	0.1 %	0.9 %
Expected dividends	—	—	—
Weighted average fair value at grant date	$ 159.44	$ 246.84	$ 96.94

We recognized stock-based compensation related to our employee stock purchase plan of $23.5 million, $12.2 million and $10.5 million for the year ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we expect to recognize $14.8 million of total unamortized compensation costs related to future employee stock purchases over a weighted average period of 0.9 year.

Note 10. Common Stock Repurchase Programs

In May 2018, our Board of Directors authorized a plan to repurchase up to $600.0 million of our common stock ("May 2018 Repurchase Program"). As of December 31, 2021, the authorization under the May 2018 Repurchase Program was completed. In May 2021, our Board of Directors authorized a plan to repurchase up to $1.0 billion of our common stock ("May 2021 Repurchase Program"). As of December 31, 2022, we have $249.9 million available for repurchases under the May 2021 Repurchase Program.

Subsequent to the fourth quarter, in January 2023, our Board of Directors authorized a plan to repurchase up to $1.0 billion of our common stock.

Accelerated Share Repurchase Agreements ("ASRs")

We entered into ASRs providing for the repurchase of our common stock based on the volume-weighted average price during the term of the agreement, less an agreed upon discount. Under the terms of the ASRs, the financial institution may be required to deliver additional shares of common stock at final settlement or, under certain circumstances, we may be required at our election, to either deliver shares or make a cash payment to the financial institution. The ASRs limit the number of shares we would be required to deliver.

The following table summarizes the information regarding repurchases of our common stock under ASRs:

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
Q2 2021	May 2018	$ 100.0	Q3 2021	171,322	$ 583.70
Q2 2021	May 2021	$ 100.0	Q3 2021	161,707	$ 618.40
Q3 2021	May 2021	$ 75.0	Q3 2021	109,239	$ 686.91
Q4 2021	May 2021	$ 100.0	Q4 2021	150,031	$ 666.53
Q2 2022	May 2021	$ 200.0	Q2 2022	756,502	$ 264.37
Q4 2022	May 2021	$ 200.0	N/A[1]	848,266	$ 188.62

[1] As of December 31, 2022, the contract was open and we recorded the remaining equity forward contract at a fair value of $40.0 million which was included within "Additional paid-in capital" in stockholders' equity in our Consolidated Balance Sheet. Subsequent to the fourth quarter, the ASR was completed and 0.1 million additional shares were received at an average price per share of $293.15.

Subsequent to the fourth quarter, on February 3, 2023, we entered into an ASR to repurchase $250.0 million of our common stock, completing our 2021 Repurchase Program. We paid $250.0 million and received an initial delivery of approximately 0.6 million shares based on current market prices. The final number of shares to be repurchased will be based on our volume-weighted average stock price under the terms of the ASR, less an agreed upon discount.

Open Market Common Stock Repurchases

During the year ended December 31, 2022, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of $522.61 per share, including commissions and fees, for an aggregate purchase price of $75.0 million.

Note 11. Employee Benefit Plans

We have defined contribution retirement plan under Section 401(k) of the Internal Revenue Code for our U.S. employees which covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. We match 50% of our employee's salary deferral contributions up to 6% of the employee's eligible compensation. We contributed approximately $10.0 million, $8.5 million and $6.9 million to the 401(k) plan during the year ended December 31, 2022, 2021 and 2020, respectively. We also have defined contribution retirement plans outside of the U.S. to which we contributed $54.5 million, $42.3 million and $28.9 million during the year ended December 31, 2022, 2021 and 2020, respectively.

Note 12. Income Taxes

Net income before provision for (benefit from) income taxes consists of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Domestic	$ 268,097	$ 378,478	$ 173,099
Foreign	330,960	633,945	205,850
Net income before provision for (benefit from) income taxes	$ 599,057	$ 1,012,423	$ 378,949

The provision for (benefit from) income taxes consists of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Federal			
Current	$ 188,050	$ 157,383	$ 55,291
Deferred	(55,579)	(25,598)	(11,749)
	132,471	131,785	43,542
State			
Current	34,621	28,365	8,862
Deferred	(12,265)	(5,860)	(2,121)
	22,356	22,505	6,741
Foreign			
Current	56,537	42,681	29,399
Deferred	26,120	43,432	(1,476,621)
	82,657	86,113	(1,447,222)
Provision for (benefit from) income taxes	$ 237,484	$ 240,403	$ (1,396,939)

The differences between income taxes using the federal statutory income tax rate for 2022, 2021 and 2020 and our effective tax rates are as follows:

	Year Ended December 31,		
	2022	2021	2020
U.S. federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State income taxes, net of federal tax benefit	3.7	2.2	1.5
U.S. tax on foreign earnings	5.6	2.5	(1.2)
Impact of differences in foreign tax rates	3.3	(2.0)	5.6
Stock-based compensation	2.1	(0.3)	1.1
Impact of intra-entity intellectual property rights transfer	—	—	(395.6)
Settlement on audits	1.9	—	(1.4)
Change in valuation allowance	1.7	1.1	0.1
Other items not individually material	0.3	(0.8)	0.3
Effective tax rate	39.6 %	23.7 %	(368.6)%

We intend to continue reinvesting our foreign subsidiary earnings indefinitely and do not expect any additional costs that we may incur upon repatriation of these foreign earnings to be significant.

During the year ended December 31, 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our new Swiss subsidiary, where our EMEA regional headquarters is located beginning January 1, 2020. The transfer of intellectual property rights did not result in a taxable gain; however, it did result in a step-up of the Swiss tax deductible basis in the transferred assets, and accordingly, created a temporary difference between the book basis and the tax basis of such intellectual property rights. Consequently, this transaction resulted in the recognition of a deferred tax asset and related one-time tax benefit of approximately $1,493.5 million during the year ended December 31, 2020, which is the net impact of the deferred tax asset recognized as a result of the additional Swiss tax deductible basis in the transferred assets and certain costs related to the transfer of fixed assets and inventory.

As of December 31, 2022 and 2021, the significant components of our deferred tax assets and liabilities are (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss and capital loss carryforwards	$ 15,380	$ 11,069
Reserves and accruals	32,759	47,641
Stock-based compensation	19,469	13,576
Deferred revenue	117,039	83,514
Capitalized research & development	54,293	413
Amortizable tax basis in intangibles	1,350,434	1,392,471
Other	16,645	15,645
Deferred tax assets before valuation allowance	1,606,019	1,564,329
Valuation allowance	(23,286)	(12,938)
Total deferred tax assets	1,582,733	1,551,391
Deferred tax liabilities:		
Depreciation and amortization	11,407	12,328
Acquisition-related intangibles	26,008	28,989
Other	3,438	6,931
Total deferred tax liabilities	40,853	48,248
Net deferred tax assets	1,541,880	1,503,143

The available positive evidence at December 31, 2022 included historical operating profits and a projection of future income sufficient to realize most of our remaining deferred tax assets. As of December 31, 2022, it was considered more likely

than not that our deferred tax assets would be realized with the exception of certain net operating loss, capital loss carryovers and unrealized translation losses as we are unable to forecast sufficient future profits to realize the deferred tax assets. The total valuation allowance as of December 31, 2022 was $23.3 million. During the year ended December 31, 2022, the valuation allowance increased by $10.3 million primarily due to deferred tax assets related to unrealized translation losses and net operating loss from one of our German subsidiaries and the deferred tax assets from our Russian commercial entity are not more likely than not to be realized.

As of December 31, 2022, we have foreign net operating loss carryforwards of approximately $48.2 million, attributed mainly to losses in China, Italy and Germany. The losses in Italy and Germany can be carried forward indefinitely. The operating loss carryforwards in China, if not utilized, will expire beginning 2026.

The changes in the balance of gross unrecognized tax benefits, which exclude interest and penalties, for the year ended December 31, 2022, 2021 and 2020, are as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Gross unrecognized tax benefits at January 1,	$ 63,295	$ 46,320	$ 46,650
Increases related to tax positions taken during the current year	84,249	27,710	20,592
Increases related to tax positions taken during a prior year	15,411	5,471	10,201
Decreases related to tax positions taken during a prior year	(2,647)	(5,804)	(29,977)
Decreases related to expiration of statute of limitations	(4,582)	(8,986)	—
Decreases related to settlement with tax authorities	(14,166)	(1,416)	(1,146)
Gross unrecognized tax benefits at December 31,	$ 141,560	$ 63,295	$ 46,320

The total amount of gross unrecognized tax benefits as of December 31, 2022 was $141.6 million, of which $134.3 million would impact our effective tax rate if recognized.

We file U.S. federal, U.S. state, and non-U.S. income tax returns. Our major tax jurisdictions include U.S. federal, the State of California and Switzerland. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2017 and 2015, respectively. Our Israeli subsidiary was under tax audit for years 2016 through 2019. During the fourth quarter of 2022, we settled the audit with the Israel Tax Authority in connection with a 2016 transaction to which our Israeli subsidiary was a party. As a result, we are no longer subject to tax examinations for years through 2021 in Israel. With few exceptions, we are no longer subject to examination by other foreign tax authorities for years before 2015.

We have elected to recognize interest and penalties related to unrecognized tax benefits as a component of income taxes. Interest and penalties included in tax expense for the year ended December 31, 2022, 2021 and 2020 as well as accrued as of December 31, 2022 and 2021 were not material. While we defend income tax audits in various jurisdictions and the results of such audits may differ materially from the amounts accrued for each year, we cannot currently ascertain the bases on which any given audit will be ultimately resolved. Accordingly, we are unable to estimate the range of possible adjustments to our balance of gross unrecognized tax benefits in the next 12 months.

Note 13. Net Income per Share

Basic net income per share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net income per share is computed using the weighted average number of shares of common stock, adjusted for any dilutive effect of potential common stock. Potential common stock, computed using the treasury stock method, includes RSUs, MSUs, PSUs and our ESPP.

The following table sets forth the computation of basic and diluted net income per share attributable to common stock (in thousands, except per share amounts):

	Year Ended December 31,		
	2022	2021	2020
Numerator:			
Net income	$ 361,573	$ 772,020	$ 1,775,888
Denominator:			
Weighted average common shares outstanding, basic	78,190	78,917	78,760
Dilutive effect of potential common stock	230	753	470
Total shares, diluted	78,420	79,670	79,230
Net income per share, basic	$ 4.62	$ 9.78	$ 22.55
Net income per share, diluted	$ 4.61	$ 9.69	$ 22.41
Anti-dilutive potential common shares [1]	320	1	280

[1] Represents stock-based awards not included in the calculation of diluted net income per share as the effect would have been anti-dilutive.

Note 14. Supplemental Cash Flow Information

The supplemental cash flow information consists of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Taxes paid	$ 231,884	$ 203,309	$ 76,332
Non-cash investing and financing activities:			
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	$ 35,767	$ 64,135	$ 37,267
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 31,015	$ 29,769	$ 26,022
Right-of-use assets obtained in exchange for lease obligations:			
Operating leases	$ 34,144	$ 68,463	$ 47,981

Note 15. Segments and Geographical Information

Segment Information

We report segment information based on the management approach. The management approach designates the internal reporting used by our Chief Operating Decision Maker for decision making and performance assessment as the basis for determining our reportable segments. The performance measures of our reportable segments include net revenues, gross profit and income from operations. Income from operations for each segment includes all geographic revenues, related cost of net revenues and operating expenses directly attributable to the segment. Certain operating expenses are attributable to operating segments and each allocation is measured differently based on the specific facts and circumstances of the costs being allocated. Costs not specifically allocated to segment income from operations generally include various corporate expenses such as stock-based compensation and costs related to IT, facilities, human resources, accounting and finance, legal and regulatory, other separately managed general and administrative costs outside the operating segments and restructuring costs. We group our operations into two reportable segments: Clear Aligner segment and Imaging Systems and CAD/CAM services (“Systems and Services”) segment.

Summarized financial information by segment is as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net revenues			
Clear Aligner	$ 3,072,585	$ 3,247,080	$ 2,101,459
Systems and Services	662,050	705,504	370,482
Total net revenues	$ 3,734,635	$ 3,952,584	$ 2,471,941
Gross profit			
Clear Aligner	$ 2,228,170	$ 2,474,373	$ 1,532,130
Systems and Services	405,605	460,982	231,105
Total gross profit	$ 2,633,775	$ 2,935,355	$ 1,763,235
Income from operations			
Clear Aligner	$ 1,134,420	$ 1,325,866	$ 768,045
Systems and Services	179,765	259,127	96,052
Unallocated corporate expenses	(671,590)	(608,593)	(476,926)
Total income from operations	$ 642,595	$ 976,400	$ 387,171
Stock-based compensation			
Clear Aligner	$ 14,816	$ 10,648	$ 8,975
Systems and Services	994	705	734
Unallocated corporate expenses	117,557	102,983	88,718
Total stock-based compensation	$ 133,367	$ 114,336	$ 98,427
Depreciation and amortization			
Clear Aligner	$ 57,888	$ 50,723	$ 41,371
Systems and Services	28,300	21,581	16,798
Unallocated corporate expenses	39,605	36,425	35,369
Total depreciation and amortization	$ 125,793	$ 108,729	$ 93,538

The following table reconciles total segment income from operations in the table above to net income before provision for (benefit from) income taxes (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Total segment income from operations	$ 1,314,185	$ 1,584,993	$ 864,097
Unallocated corporate expenses	(671,590)	(608,593)	(476,926)
Total income from operations	642,595	976,400	387,171
Interest income	5,367	3,103	3,125
Other income (expense), net	(48,905)	32,920	(11,347)
Net income before provision for (benefit from) income taxes	$ 599,057	$ 1,012,423	$ 378,949

Geographical Information

Net revenues are presented below by geographic area (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net revenues [1]:			
U.S.	$ 1,660,045	$ 1,724,296	$ 1,099,564
Switzerland	1,216,094	1,353,229	809,080
Other International	858,496	875,059	563,297
Total net revenues	$ 3,734,635	$ 3,952,584	$ 2,471,941

[1] Net revenues are attributed to countries based on the location of where revenues are recognized by our legal entities.

Tangible long-lived assets, which includes Property, plant and equipment, net, and Operating lease right-of-use assets, net, are presented below by geographic area (in thousands):

	December 31,	
	2022	2021
Long-lived assets [1]:		
Switzerland	$ 532,921	$ 444,205
U.S.	214,804	210,582
China	118,669	125,346
Other International	484,341	423,050
Total long-lived assets	$ 1,350,735	$ 1,203,183

[1] Long-lived assets are attributed to countries based on the location of our entity that owns or leases the assets.

Note 16. Restructuring and Other Charges

Restructuring Activities

During the fourth quarter of 2022, we initiated a restructuring plan to increase efficiencies across the organization which is expected to be completed in the first half of 2023. We incurred approximately $10.2 million in restructuring expenses, of which $2.9 million was recorded in Cost of net revenues and $7.3 million was recorded in Restructuring and other charges.

Activity related to the restructuring liabilities associated with our restructuring initiatives consist of the following (in thousands):

	Severance and related costs	Impairment Charges	Total
Restructuring charges	$ 8,723	$ 1,453	$ 10,176
Cash payments	(4,807)	—	(4,807)
Non-cash charges	—	(1,453)	(1,453)
Balance as of December 31, 2022 [1]	$ 3,916	$ —	$ 3,916

[1] Included in "Accrued liabilities" within our Consolidated Balance Sheet.

Other Charges

In addition to the restructuring charges, during the fourth quarter of 2022, we also incurred certain lease termination costs of $2.3 million and asset impairments of $1.8 million which were also recorded in Restructuring and other charges.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of December 31, 2022 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

Management's annual report on internal control over financial reporting.

See "Report of Management on Internal Control over Financial Reporting" of this Annual Report on Form 10-K.

Changes in internal control over financial reporting.

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement for our 2023 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included therein is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by Item 401 of Regulation S-K concerning our directors is incorporated by reference to the Proxy Statement under the section captioned "Directors." The information required by Item 401 of Regulation S-K concerning our executive officers is set forth in *Item 1— "Business" of this Annual Report on Form 10-K*. The information required by Item 405 of Regulation S-K is incorporated by reference to the section entitled "Delinquent Section 16(a) Reports" contained in the Proxy Statement. The information required by Item 407(c)(3), 407(d)(4) and 407(d)(5) of Regulation S-K is incorporated by reference to the Proxy Statement under the section entitled "Corporate Governance".

Code of Ethics

We have a code of ethics (which we call our Global Code of Conduct) that applies to all of our employees, including our principal executive officer, principal financial officer and controller. Our Global Code of Conduct is posted on the investor relations portion of our website at *http://investor.aligntech.com* within the section captioned "Corporate Governance".

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by posting such information on our website, at the address and location specified above, or as otherwise required by the NASDAQ Global Select Market.

Item 11. Executive Compensation.

The information required by Item 402 of Regulation S-K is incorporated by reference to the Proxy Statement under the section captioned "Executive Compensation - Compensation Discussion and Analysis." The information required by Items 407(e)(4) and (e)(5) is incorporated by reference to the Proxy Statement under the section captioned "Corporate Governance - Committee Oversight - Compensation Committee Interlocks and Insider Participation" and "Compensation Committee of the Board Report," respectively.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by Item 403 and Item 201(d) of Regulation S-K is incorporated by reference to the Proxy Statement under the sections captioned "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information," respectively.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by Item 404 and Item 407 of Regulation S-K is incorporated by reference to the Proxy Statement under the sections captioned "Certain Relationships and Related Party Transactions" and "Corporate Governance— Board and Committee Independence and Qualifications," respectively.

Item 14. Principal Accountant Fees and Services.

The information required by Item 9(e) of Schedule 14A of the Securities Act of 1934, as amended, is incorporated by reference to the Proxy Statement under the section captioned "Ratification of Appointment of Independent Registered Public Accountants."

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a) Financial Statements

1. Consolidated financial statements

The following documents are filed as part of this Annual Report on Form 10-K:

2. The following financial statement schedule is filed as part of this Annual Report on Form 10-K:

Schedule II—Valuation and Qualifying Accounts and Reserves for the year ended December 31, 2022, 2021 and 2020

All other schedules have been omitted as they are not required, not applicable, or the required information is otherwise included.

SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

	Balance at Beginning of Period	Additions (Reductions) to Costs and Expenses	Write Offs	Balance at End of Period
		(in thousands)		
Allowance for doubtful accounts:				
Year Ended December 31, 2020	$ 6,756	$ 12,073	$ (8,590)	$ 10,239
Year Ended December 31, 2021	$ 10,239	$ 2,814	$ (3,808)	$ 9,245
Year Ended December 31, 2022	$ 9,245	$ 4,102	$ (3,004)	$ 10,343
Valuation allowance for deferred tax assets:				
Year Ended December 31, 2020	$ 1,086	$ 239	$ —	$ 1,325
Year Ended December 31, 2021	$ 1,325	$ 11,613	$ —	$ 12,938
Year Ended December 31, 2022	$ 12,938	$ 10,348	$ —	$ 23,286

(b) The following Exhibits are included in this Annual Report on Form 10-K:

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
3.1	Amended and Restated Certificate of Incorporation of registrant	S-1, as amended (File No. 333-49932)	12/28/2000	3.1	
3.1A	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	5/20/2016	3.01	
3.2	Amended and Restated Bylaws of registrant	8-K	2/29/2012	3.2	
3.2A	Amendment to Amended and Restated Bylaws of registrant	Def 14A	4/7/2021	1.0	
4.1	Form of Specimen Common Stock Certificate	S-1, as amended (File No. 333-49932)	1/17/2001	4.1	
4.2	Description of the Capital Stock of registrant	10-K	2/28/2020	4.2	
10.1A†	Registrant's 2010 Employee Stock Purchase Plan (as amended and restated as of May 19, 2021)	8-K	5/20/2021	10.1	
10.2†	Registrant's 2005 Incentive Plan (as amended May 2016)	10-K	2/26/2021	10.2	
10.3†	Form of RSU agreement under Registrant's 2005 Incentive Plan (Officer Form for officers appointed after September 2016)	10-K	2/28/2020	10.3	
10.3A†	Form of RSU agreement under Registrant's 2005 Incentive Plan (Officer Form for officers appointed prior to September 2016)	10-K	2/28/2020	10.3A	
10.4†	Form of RSU agreement (CEO)	10-K	2/28/2020	10.4	
10.5†	Form of RSU agreement under Registrant's 2005 Incentive Plan (Non-employee Director Form)	10-K	2/28/2020	10.5	
10.6†	Align 2019 Global RSU Agreement	10-K	2/28/2019	10.6	
10.7†	Form of option award agreement under registrant's 2005 Incentive Plan	10-Q	8/4/2005	10.4	
10.8†	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2019, 2020 and 2022 to officers appointed after September 2016)	10-K	2/28/2020	10.8	
10.8A†	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2019, 2020 and 2022 to officers appointed prior to September 2016)	10-K	2/28/2020	10.8A	
10.9†	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2021 to officers appointed after September 2016)	10-K	2/26/2021	10.9	
10.9A†	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2021 to officers appointed prior to September 2016)	10-K	2/26/2021	10.9A	
10.10†	Form of Market Stock Unit Agreement for CEO (Focal grants)	10-K	2/28/2020	10.9	
10.11†	Form of Employment Agreement entered into by and between registrant and each executive officer (other than CEO for executives appointed prior to September 2016)	10-Q	5/8/2008	10.3	
10.12†	Form of Employment Agreement entered into by and between registrant and each executive officer (other than CEO for executives appointed after September 2016)	10-K	2/28/2017	10.8	
10.13†	Amended and Restated Chief Executive Officer Employment Agreement between Align Technology, Inc. and Joseph Hogan	10-Q	5/1/2015	10.30	
10.14†	Employment Agreement between registrant and John F. Morici (Chief Financial Officer)	10-Q	11/8/2016	10.2	
10.15†	Form of Indemnification Agreement by and between registrant and its Board of Directors and its executive officers	S-1 as amended (File No. 333-49932)	1/17/2001	10.15	
10.16	Sale and Purchase Agreement between CETP III Ivory S.a.r.l., and Align Technology, Inc. and its indirect wholly owned German subsidiary, mertus 602.GmbH, dated March 3, 2020	10-Q	5/5/2020	10.1	

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
10.17	Credit Agreement between Align Technology, Inc. and the lenders party thereto from time to time and Citibank, N.A., as administrative agent, dated July 21, 2020	10-Q	10/30/2020	10.1	
10.18	First Amendment, dated April 21, 2022, to Credit Agreement between Align Technology, Inc. and the lenders party thereto from time to time and Citibank, N.A., as administrative agent, dated July 21, 2020				*
10.19	Second Amendment, dated December 23, 2022, to Credit Agreement between Align Technology, Inc. and the lenders party thereto from time to time and Citibank, N.A., as administrative agent, dated July 21, 2020				*
10.20	Fixed Dollar Accelerated Share Repurchase Transaction between Goldman Sachs & Co. LLC and Align Technology, Inc. dated October 28, 2022				*
21.1	Subsidiaries of Align Technology, Inc.				*
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm				*
31.1	Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003				*
31.2	Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003				*
32♦	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003				*
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).				*
101.SCH	Inline XBRL Taxonomy Extension Schema Document				*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				*

† Management contract or compensatory plan or arrangement filed as an Exhibit to this form pursuant to Items 14(a) and 14(c) of Form 10-K.

♦ Furnished herewith

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALIGN TECHNOLOGY, INC.

By: /S/ JOSEPH M. HOGAN
Joseph M. Hogan
President and Chief Executive Officer

Date: **February 27, 2023**

Each person whose signature appears below constitutes and appoints Joseph M. Hogan or John F. Morici, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ JOSEPH M. HOGAN **Joseph M. Hogan**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2023
/S/ JOHN F. MORICI **John F. Morici**	Chief Financial Officer and Executive Vice President, Global Finance (Principal Financial Officer and Principal Accounting Officer)	February 27, 2023
/S/ KEVIN J. DALLAS **Kevin J. Dallas**	Director	February 27, 2023
/S/ JOSEPH LACOB **Joseph Lacob**	Director	February 27, 2023
/S/ C. RAYMOND LARKIN, JR. **C. Raymond Larkin, Jr.**	Director	February 27, 2023
/S/ GEORGE J. MORROW **George J. Morrow**	Director	February 27, 2023
/S/ ANNE M. MYONG **Anne M. Myong**	Director	February 27, 2023
/S/ ANDREA L. SAIA **Andrea L. Saia**	Director	February 27, 2023
/S/ GREG J. SANTORA **Greg J. Santora**	Director	February 27, 2023
/S/ SUSAN E. SIEGEL **Susan E. Siegel**	Director	February 27, 2023
/S/ WARREN S. THALER **Warren S. Thaler**	Director	February 27, 2023