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, 2023

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 $13.7 billion as of June 30, 2023 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 22, 2024, 75,104,132 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2024 Annual Stockholders' Meeting to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year end of December 31, 2023 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, 2023
TABLE OF CONTENTS

		Page
PART I		3
Item 1.	Business	3
	Information about our Executive Officers	20
Item 1A.	Risk Factors	20
Item 1B.	Unresolved Staff Comments	35
Item 1C.	Cybersecurity	35
Item 2.	Properties	36
Item 3.	Legal Proceedings	36
Item 4.	Mine Safety Disclosures	36
PART II		37
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	37
Item 6.	[Reserved]	38
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	38
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	50
Item 8.	Financial Statements and Supplementary Data	52
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	89
Item 9A.	Controls and Procedures	89
Item 9B.	Other Information	89
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	89
PART III		89
Item 10.	Directors, Executive Officers and Corporate Governance	89
Item 11.	Executive Compensation	90
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	90
Item 13.	Certain Relationships and Related Transactions and Director Independence	90
Item 14.	Principal Accountant Fees and Services	90
PART IV		92
Item 15.	Exhibits and Financial Statement Schedules	92
Item 16.	Form 10-K Summary	95
Signatures		96

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 product mix and product adoption, our expectations regarding competition and our ability to compete in our target markets, our expectations regarding the sales growth of our intraoral scanners, clear aligners and other products, our expectations regarding the impact of the military conflicts in the Middle East and Ukraine and our operations and assets in Israel and Russia, 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 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 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 productivity impact 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 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 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, consumers, orthodontists, 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, 2023, Clear Aligner net revenues represented approximately 83% of worldwide net revenues, while Systems and Services net revenues represented the remaining 17%. We sell the majority of our products directly through a dedicated and specialized sales force to our customers: orthodontists, GPs, including prosthodontists, periodontists, 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. We also sell our products to dental laboratories who use our products to manufacture or customize their own products for licensed dentists. We also market and sell doctor and consumer accessory products complementary to our doctor-prescribed principal products under the Invisalign® and other brands, including retainers, dental supplies, clear 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 they expect and the results patients desire. To date, approximately 17 million people worldwide have been treated with the 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, with the goal to provide 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 designed to improve all aspects of treatment, from initial consultations to final smiles with our doctor-centered treatment model. The Align Digital Platform 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 that includes the following key components:

Workflow.jpg

- **Connect:** The initial stage of the platform drives consumer demand and connects potential patients to our websites and the websites of Invisalign providers. Some of the 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. Doctors and their staffs use intraoral scanning tools designed to support diagnosis of a patient's oral conditions and health and support doctors to develop appropriate treatment pathways. Visualization of their potential smiles 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, Invisalign SmileView™ tool, iTero Element™ 5D auto upload feature, iTero™ Scan Report and iTero exocad Connector™.
- **Diagnose**: Doctors can access and use tools that support diagnosis of a patient's oral health and develop an appropriate treatment pathway. The Align Digital Platform facilitates the doctor-patient conversation, through education regarding clinical needs and setting expectations. Some of the tools that support this stage include Align™ Oral Health Suite, iTero™ NIRI technology (Near Infra-Red Imaging), iTero™ TimeLapse technology and iTero Occlusogram.
- **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 desired outcomes. Some of the tools that support this stage are ClinCheck Pro® 6.0, ClinCheck® In-Face Visualization, ClinCheck® Live Update, Invisalign® Practice App, Invisalign® Personalized Plan, CBCT integration for ClinCheck® software, Invisalign Smile Architect™ and exocad Dental CAD™ software.
- **Treat:** During this stage, doctors treat their patients with our Invisalign® clear aligners and may offer teeth whitening using the Invisalign™ Professional Whitening System.
- **Monitor:** Doctors can remotely track their patients' treatment between visits, and orthodontists and GPs can more easily track treatment progress and communicate issues, results and recommendations to their patients. Some of the 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:** Following completion of their orthodontic treatment, patients can retain the final position of their teeth using Vivera™ retainers.

As we further evolve the treatment planning experience for doctors through new 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 2023, we launched several new products and technologies that further enhance the Align Digital Platform, including the enhanced precision wings for Invisalign treatment with mandibular advancement, the Invisalign®

Palatal Expander system, the SmartForce™ attachment-free clear aligner activation feature, the Plan Editor in ClinCheck® treatment planning software, the Align™ Oral Health Suite, iTero-exocad Connector™, exoplan 3.1 Rijeka, ChairsideCAD 3.1 Rijeka, PartialCAD 3.1 Rijeka, and Invisalign™ Lens.

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 600 million people globally with malocclusion who could benefit from straightening their teeth. However, most people afflicted by malocclusion do not seek orthodontic treatment for various reasons, including negative perceptions of metal braces, affordability of treatment, and accessibility to doctors. Annually, only approximately 22 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 treatment. Of the 22 million cases started each year, we estimate that almost all can be treated using our Invisalign system, yet our share of the 22 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, increasing utilization of existing doctors using our products, 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. As part of the Align™ Digital Workflow, Align has developed solutions to enable doctor diagnosis and drive patient conversion – providing tools to support diagnosis of a patients’ oral health and support to identify an appropriate treatment pathway, facilitating the doctor-patient conversation, education and clinical needs and expectations. 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 91% of Invisalign system prescription orders are now submitted via digital scan, increasing the accuracy of treatment plans, reducing the time from when the doctor submits the prescription to the time the patient receives the clear aligners, and helping to decrease the carbon footprint resulting from elimination of the initial or upfront shipment of the patient’s PVS impressions to the doctors and shipping those PVS impressions back to us.

Computer-simulated treatment plan. Our ClinCheck® treatment planning software is the cornerstone of the Align Digital Platform. ClinCheck Pro treatment planning software uses proprietary algorithms based on the insights from data from our more than 17 million patients treated worldwide. 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 shapes 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 clear aligners. Following the dental professional’s approval of a ClinCheck treatment plan, we use the data underlying the simulation as input in which we use stereolithography technology (a form of 3D printing technology) to construct a series of molds. Each mold is a replica of the patient’s teeth at each stage of the simulated course of treatment. From these molds, clear aligners are fabricated by pressure-forming polymeric sheets over each mold. Clear 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 clear aligner wear. Once manufactured, all the clear aligners for a patient's doctor-approved treatment plan are typically shipped directly to the dental professional. The majority of doctors then dispense all of the clear aligners to the patient. Clear aligners are generally worn for one week or 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 their current set of clear 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 order additional clear aligners for refinements.

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 and also designed on nonclinical needs. 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**	arro6.jpg	**Moderate**	arro5.jpg	**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 clear aligners if the patient's treatment deviates from the original treatment plan. The number and timing of additional clear 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.

In the first quarter of 2023, we launched the Invisalign Comprehensive 3in3 product. The 3in3 configuration offers doctors Invisalign Comprehensive treatment with a three-year treatment expiration date and three additional clear aligners included prior to the treatment expiration date, instead of a five-year treatment expiration date with unlimited additional clear aligner sets prior to the treatment end date. Invisalign Comprehensive 3in3 product is available in North America and in certain markets in EMEA and APAC, most recently launching in China, Korea, Hong Kong and Taiwan.

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, and Invisalign® Moderate. These packages may be offered in select countries and/or may differ from region to region.

Invisalign Doctor Subscription Program (“DSP”) is our monthly subscription-based clear aligner program which includes retainers and low-stage “touch-up” clear aligner treatment. As of September 31, 2023, Invisalign DSP touch-up cases have been reclassified to non-comprehensive cases and are now reflected in our reported case volumes and metrics. Prior to this quarter, they were reported in the non-case category. DSP is currently available in the U.S., Canada, Iberia, Nordics and, most recently in the UK.

Invisalign Go Packages. In various markets we also offer Invisalign Go™, Invisalign Go™ Express 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.

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.

Invisalign Professional Whitening System. Additionally, we offer a professional whitening system using Ultradent’s Opalescence PF whitening system with Vivera retainers.

New Products/Feature Enhancement

Invisalign® Palatal Expander. In December 2023, we received 510(k) clearance in the U.S. for the Invisalign Palatal Expanders.The Invisalign Palatal Expander System is intended for use in rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw) with primary, mixed, or permanent dentition during patient treatment. It provides an alternative to traditional palatal expanders that require the daily manual turning of a screw in the device in the mouth to achieve expansion. The Invisalign Palatal Expander is our first direct 3D printed orthodontic device. Combined with Invisalign First™ aligners, Invisalign Palatal Expanders provide doctors with a full early intervention treatment solution such as Phase 1 or early interceptive treatment, traditionally done through arch expanders or partial metal braces, before all permanent teeth have erupted. The Invisalign Palatal Expander is currently available on a limited basis in Canada and the U.S.

In January 2024, we completed the acquisition of Cubicure GmbH (“Cubicure”), a company that develops, produces and distributes innovative materials, equipment and processes for novel 3D printing solutions. Cubicure’s patented Hot Lithography technology uses a special heating and coating mechanism that enables the processing of highly viscous resins to produce tough and temperature-resistant polymers. We believe that the acquisition of Cubicure will support our long-term growth strategy by enabling us to scale our 3D

printing operations to eventually direct print millions of custom appliances per day. We expect the acquisition of Cubicure will ultimately extend and scale our printing, materials and manufacturing capabilities for our 3D printed products while concurrently materially reducing the amount of resin used in our manufacturing process.

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 clear aligner is shaped so that when inserted, the clear 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 clear 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 clear 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 clear 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 substantially impacting the practice of dentistry. By enabling the dental practitioner to create a 3D image (digital scan) of a patient's teeth using a handheld intraoral scanner, digital scanning is faster, more efficient, precise and comfortable for patients. Beginning patient care with the early use 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, iTero Element™ Plus Series and the iTero Lumina™ 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 iTero-exocad Connector™.

In January 2024, we launched the iTero Lumina intraoral scanner. The iTero Lumina intraoral scanner is designed with iTero Multi-Direct Capture™ technology that we believe quickly, easily, and accurately captures more data while delivering exceptional scan quality and photorealistic images that eliminate the need for intraoral photos altogether. iTero Multi-Direct Capture replaces the confocal imaging technology in earlier intraoral scanner models. It has a wider field of capture and multi-angled scanning that enables simultaneous capture from multiple angles. Additionally, the iTero Lumina scanner has a capture distance of up to 25mm, making it easier to scan complex oral regions such as narrow or deep palates, edentulous spaces, and partially erupted teeth. It has a 50% smaller and 45% lighter wand (as compared to iTero Element™ 5D imaging system wand, excluding the wand cable), which is expected to be especially beneficial for kids and teen patients. The iTero Lumina scanner has photorealistic scans which enables high quality clinical decisions the same way intraoral photos do and its advanced software enables scanning at two times the speed.

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.

Align™ Oral Heatlh Suite. The Align™ Oral Health Suite is a digital interface designed to enhance dental consultations. It offers a modern approach to dental examinations, featuring a clinical framework that is designed to empower doctors and their clinic staff to conduct comprehensive oral health assessments via a single scan using patient-friendly terminology, and providing a highly engaging patient-centric experience. It integrates iTero diagnostic aid and visualization tools, such as iTero NIRI, iTero Occlusogram, iTero TimeLapse and Invisalign Outcome Simulator Pro into a single interface chairside on the iTero scanner.

CAD/CAM Services. 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, Align X-Ray Insights 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

Over the past 26 years, Align has helped doctors treat approximately 17 million patients with the Invisalign system and is driving the evolution in digital dentistry through the Align Digital Platform™. 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 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. As of the end of 2023, we are 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. As of the end of 2023, we have 13 fabrication and treatment locations throughout the world. We have a manufacturing facility in each of our three key regions: Americas (Mexico), APAC (China), and EMEA (Poland). Each of these three facilities represents a “hub” in our “Regional Hub Model” and together they form the foundation of our manufacturing strategy, which will continue to evolve to increase flexibility and optimize our capacity and cost structure. 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 2024 by investing in resources, infrastructure and initiatives that help drive Invisalign treatment growth, position our intraoral scanners as the preferred scanning technology for digital

dental scans, and establish our exocad CAD/CAM software as the solution of choice for dental labs in existing and new international markets.

- GP Dentist Treatment. 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 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 which 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.

- Patient Demand. 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 600 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 2023, 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 22 million annual orthodontic case starts. 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 regional fabrication facilities in our main markets for clear aligners, which are located in Juarez, Mexico; Ziyang, China; and Wroclaw, Poland. We have designed this Regional Hub Model to better serve our global customer base by being closer to our doctor customers and driving 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 clear 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. Moreover, 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 clear 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 adjust and 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 clear 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 clear 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, 2023, we had approximately 125,800 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 as part of 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, more than 200 peer-reviewed publications and various clinical case studies and articles have been published that highlight the clinical applicability of Invisalign treatment to malocclusion cases, including addressing malocclusions 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 14th year in 2023 and donations to the American Association of Orthodontists Foundation.

Intellectual Property

We believe our intellectual property portfolio represents a substantial business advantage. As of December 31, 2023, we had 866 active U.S. patents, 954 active foreign patents, and 884 pending global patent applications. Our active U.S. patents expire between 2024 and 2042. 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 the first quarter. 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 start their children in treatment before the school year begins. Conversely, 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 changes in foreign exchange rates, military conflicts, and inflation and other macroeconomic challenges. It remains unclear when or if our seasonal fluctuations will return to historical norms.

Competition

Competition in the clear aligner market continues to increase. 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. We also compete with direct-to-consumer (“DTC”) companies that provide

clear aligners directly to the consumer requiring little or no in-office care from doctors and also from doctors themselves who can manufacture retainers and custom clear aligners using 3D printing technology. In addition, corresponding foreign patents began expiring in 2018 which has increased competition outside the U.S.

Additionally, we face competition in the 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 playing larger roles. The iTero intraoral scanner also competes with traditional 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 thousands of dedicated, highly skilled sales force 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, strong workforce, diversified and knowledgeable customer base, geographic expansion, reliable financial results, leading digital platform, technology and IP, next wave of innovation with direct 3D printing and innovations powered by AI enabling more personalized care, and regulatory clearance of our products 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 and new software and artificial intelligence 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, other decision makers or purchasers of medical devices and government officials; setting out rules for when and how to engage healthcare professionals as our third-party 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 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 do or will soon regulate or restrict cross border data transfers, such as in the EU, Switzerland, U.S. Federal and States, Brazil, China, Vietnam, 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 our global privacy program framework incorporate new country and state laws so that our product innovations comply with these increasingly complex laws.

We also have information security, privacy and 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 information technology (“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.”

Environmental Laws and Regulations

We are subject to numerous international, federal, state and local environmental laws, including provisions that regulate the purchase, use, distribution, and environmental impact of hazardous substances used in our operations, contained within our products and the packaging associated with our products. We are also subject to environmental laws applicable to our manufacturing facilities and operations, including environmental health and safety regulations. The number and rate at which these regulations are being proposed and implemented are increasing at the regional, country and local territorial levels, requiring greater diligence, governance and skills to manage. We may be required to incur significant costs to comply with existing and new laws and regulations in the future. Information

regarding risks associated with environmental laws and regulations may be found in 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, 2023, we had approximately 21,610 employees, a decrease of approximately 6.7% and 4.1% over December 31, 2022, and December 31, 2021, respectively. The number of employees for each of the last five years and our employees’ roles as of December 31, 2023 are as follows:

Employees.jpg 2023 Employee Roles.jpg

We are a global organization with more than 90% of our employees located internationally, primarily in direct-labor roles in our manufacturing and clinical treatment planning facilities. Set forth in the following paragraphs are some of the most important elements of our culture and commitment to our employees.

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

As part of our Board's commitment to our environmental, social and governance ("ESG") efforts, the Board has 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 monitor trends on issues such as our total headcount, recruiting, attrition, career development, diversity, inclusion and belonging, 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 employees bring a positive mix of ethnic and culturally diverse backgrounds to the more than 40 different countries in which we operate. Our largest population of employees work in our Mexico site followed by Costa Rica and China. The United States represents approximately 10% of our global population.

2023 Location of Employees.jpg

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 provide employee experiences that encourage inclusion and diversity. We were recognized in Newsweek's list of America's Greatest Workplaces for Diversity in 2024.

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 and feel they belong.

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. Some of the certifications, awards and recognitions recognized or received in 2023 and 2024 include:

- Best Places to Work for Women in Korea
- 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
- Dun & Bradstreet Top Tech Companies to Work for in Israel
- Great Places to Work and Best Places to Work based on our employee-validated great workplaces in the following countries, Australia, Brazil, China, Costa Rica, Germany, India, Italy, Korea, Singapore, Taiwan, Thailand, UK, Vietnam and United States (Raleigh, North Carolina)
- Forbes World's Best Employers
- LinkedIn Top Companies to Grow Your Career in Israel and Poland
- Mercer Outstanding Women Care Award in China
- U.S. News & World Report- Best Companies to Work For and Best Companies to Work For in the Health Care Industry

We believe it is imperative to provide a vibrant employee experience and we value our employees' collective voices. Accordingly, we conduct employee surveys 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 2023, after years of focusing on an annual census survey where we consistently had high response rates and high scores in overall engagement, we moved to a continuous employee listening strategy. This listening strategy includes globally managed pulse surveys, employee lifecycle surveys, and a self-service feature to support listening efforts for our global employees. We use information learned from our surveys to improve the employee experience, including enhancements to our workplaces, focus on employee connections, increased career development opportunities, support for relocated employees, and growth in our recognition programs and experiences.

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 all applicable statutory and regulatory requirements and that training is routinely refreshed and re-administered.

At Align, we believe employees learn best when skill development is driven by the changing and immediate needs of our employees and by the empowerment of all employees to take action and ownership of their careers. We also believe learning should be relevant and actionable as well as rooted in our purpose and values. Develop@Align enables our global employee population to access a diverse portfolio of approximately 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. The ways in which we work, collaborate, and develop has transformed in recent years and will continue to change and evolve rapidly. We recognize that we must provide employees with the resources to continue to learn, grow, and thrive. We created Voyage as a global initiative to serve this purpose. Voyage offers a set of tools, resources and a new mindset, empowering employees to start thinking differently about career growth by embracing development opportunities in new and sometimes unexpected ways. Our Voyage Compass helps employees experience their career through four distinct lenses: Self, Networks, Experience and Skills. Since its launch, over 45% of the employee population has interacted with Voyage, and there have been over 108,000 visits to the Voyage website. In addition to our navigation site, we host two Voyage Set Sail weeks annually, where we offer experiential learning for individuals and teams utilizing activities that help keep professional development front and center in employees' minds.

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-based 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 employees 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 clear 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 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 2023, 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 2023:

- We were honored as a “Technology Partner of the Year” by Junior Achievement, 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 including hosting the first artificial intelligence career summit for around 200 high school students in our San Jose, California office.

- 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. For the third year, we sponsored Operation Smile's International Student Leadership Conference, a powerful opportunity for high schoolers around the world to develop leadership skills and impact their communities. As part of our sponsorship, we provided scholarships for 24 participants from 8 different countries, plus an additional 10 scholarships for students personally impacted with a cleft condition. As of December 31, 2023, we had donated approximately $2.7 million to Operation Smile.

- For 16 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, 2023, we have provided almost $2 million for the foundation's operational expenses and children's oral health programs. As a result of our support, more than 1.3 million children living with restricted access to care in communities across the country received dental care and/or oral health instruction through America's ToothFairy programs and the safety-net dental clinics they support.

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 28, 2024:

Name	Age	Position	Period
Joseph M. Hogan Joe Hogan ALIGNTECH June2021-6260.jpg	66	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 John Morici June2021-6316.jpg	57	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 North America Home Entertainment • Chief Financial Officer/ Chief Operating Officer of NBC Universal North America Home Entertainment • Senior Vice President and Chief Financial Officer of NBC Universal North America Home Entertainment	2022-Present 2018-2022 2016-2018 2014-2016 2011-2014 2007-2011
Julie Coletti ALIGNTECH June2021-6433.jpg	56	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 Hockridge.jpg	52	Executive Vice President, Global Human Resources of Align • Senior Vice Present, Global Human Resources of Align • Vice President, Global	2022-Present 2018-2022 2016-2018 2013-2016

Item 1A. Risk Factors.

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

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 general economic weakness and threats, or actual recessions, have and could in the future materially affect our business, results of operations, and financial condition.

Macroeconomic conditions impact consumer confidence and discretionary spending, which can adversely affect demand for our products. Consumer spending habits are affected by, among other things, inflation, fluctuations in currency exchange rates, general economic weakness, threats or actual recessions, pandemics, wars and military actions, employment levels, wages, debt obligations, discretionary income, interest rates, volatility in capital, and consumer confidence and perceptions of

current and future economic conditions. Macroeconomic conditions can, among other things, reduce or shift spending away from elective procedures, drive patients to pursue less costly orthodontic treatments, decrease the number of orthodontic case starts, reduce patient traffic in dentists' offices or reduce demand for dental services generally. Further, decreased demand for dental services can cause dentists and labs to postpone investments in capital equipment, such as intraoral scanners and CAD/CAM equipment and software. The declines in, or uncertain economic outlooks for, the U.S., Chinese, European and certain other international economies have and may continue to adversely affect consumer and dental practice spending. Increases in the cost of fuel and energy, food and other essential items as well as higher interest rates have and may continue to reduce consumers' disposable income, which could cause a decrease in discretionary spending for products like ours. Further, we cannot predict the impact of efforts by central banks and federal, state and local governments to combat inflation, which could result in an economic recession or have an adverse impact on consumer spending may for a prolonged period of time.

Inflation continues to adversely impact spending and trade activities, causing unpredictable impacts on global and regional economies. Higher inflation has also increased domestic and international shipping costs, raw material prices, and labor rates, which has adversely impacted the costs of producing, procuring and shipping our products. Our ability to recover these cost increases through price increases may continue to lag, resulting in downward pressure on our operating results. Attempts to offset cost increases with price increases may reduce sales, increase customer dissatisfaction or otherwise harm our reputation. Any of these events could materially affect our business and operating results.

We have significant international operations and sales and we are exposed to fluctuations in foreign currencies that have adversely impacted our business or results of operations. Although the U.S. dollar is our reporting currency, a large portion of our expenses, net revenues and net income are generated in foreign currencies. While we utilize forward contracts to moderate the impact of exchange rate fluctuations on certain assets and liabilities, our hedging strategies may not be successful, and currency exchange rate fluctuations have and may continue to materially adversely effect our operating results and cash flows. In addition, our foreign currency exposure on assets, liabilities and cash flows that we do not hedge have and could in the future materially impact our financial results in periods when the U.S. dollar significantly fluctuates in relation to foreign currencies.

Our business could be impacted by geopolitical events, trade and other international disputes, war, and terrorism, or major public health crises.

Political events, trade and other international disputes, war and terrorism, or major public health crises have and could in the future harm or disrupt international commerce and the global economy and could materially effect our business as well as our customers, suppliers, contract manufacturers, distributors, and other business partners. Such risks include supply chain and trade disruptions, tariffs, trade sanctions or restrictions, boycotts, reduced consumer spending, government shut downs, or cyberattacks, energy shortages or power outages, energy rationing that adversely impacts our manufacturing facilities, rising fuel or rising costs of producing, procuring and shipping our products, constraints, volatility or disruption in the financial markets, deaths or injuries to our employees, restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures or destruction of property.

Tariffs, such as those on Chinese goods, and responses to the tariffs may increase the cost of our products and the components and raw materials used to make them. Increased costs could adversely impact our gross margin and reduce demand for our products. Countries may also adopt other measures, such as controls on the import or export of goods, technology or data, that would adversely impact our operations and supply chains or limit our ability to offer products and services. These measures could require us to take various actions, including changing suppliers or restructuring business relationships. Complying with new or changed trade restrictions is expensive, time-consuming and disruptive to our operations. Such restrictions can be announced with little or no advance notice and we may be unable to effectively mitigate any adverse impacts.

Political events, trade and other international disputes, war, terrorism, or major public health crises involving key commercial, development or manufacturing markets such as China, Mexico, Israel, Europe, or other countries have and could again materially impact our international operations. The impact to us, our employees and customers would be uncertain, particularly if emergency circumstances, armed conflicts or an escalation in political instability or violence, or viral out-breaks disrupt our product development, data or information exchange, payroll or banking operations, product or materials shipping by us or our suppliers. Our internation operations would also be impacted by other unanticipated business disruptions, interruptions and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure.

Military conflicts and global pandemics have materially adversely impacted our global economies. For example, our commercial operations in Russia were impacted by the conflict in Ukraine and we were affected by the COVID-19 pandemic. Our iTero operations, headquartered in Israel, are close to areas that have been affected by ongoing violence and military action in the Middle East and this may impact our employees as well as our iTero business. Some employees and consultants in Israel have been called for military service in the current conflict in the Middle East and they may be absent for an unknown period of time. Furthermore, our facility may be damaged or supply chains impaired as a result of hostilities which could disrupt ongoing operations and impact our financial results. The conflict in the Middle East may materially impact the timing and cost of shipping of our products, our ability to operate out of Israel, or lead to sanctions or boycotts which could impact our sales and

revenues. Additionally, the recent election in Taiwan and China's territorial conflicts with other neighboring countries may impact our operations and sales in China. We cannot predict the progress or outcome of these events or the reactions by governments, businesses or consumers but they could materially adversely affect our business and operating results.

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 our operations as well as those of our customers and suppliers. Natural disasters include earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, and extreme weather conditions that cause deaths, injuries, and critical health crises, power outages, property damage restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures, materials scarcity, price volatility and other ramifications. Climate change is likely to increase the frequency and severity of natural disasters and, consequently, the risks to our operations and financial results. Our digital dental modeling and certain of our customer facing operations are primarily processed in our facilities in Costa Rica, our iTero scanners are primarily manufactured in China and Israel, and our aligner molds and finished aligners are fabricated in China, Mexico and Poland. These zones are susceptible to natural disasters and their indirect effects. If a natural disaster occurs in a region where one of these facilities or those of our customers or suppliers are located, our employees could be impacted, research lost, and ability to create treatment plans, respond to customer inquiries or manufacture and ship our aligners or intraoral scanners could be compromised, causing significant product and services delays.

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

Business and Industry Risks

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

Our products require our customers to change from traditional treatment methods. For example, Invisalign treatment is a significant change from traditional orthodontic metal wires and brackets, and customers and consumers may not find it cost-effective or preferable. A number of dental professionals believe Invisalign treatment is only appropriate for a limited percentage of patients. Additionally, our clear aligners and iTero products utilize digital technology and some dental professionals have been and may continue to resist moving to a digital platform. Increased acceptance of our products depends in part on the recommendations of dental professionals, as well as other factors including efficacy, safety, ease of use, reliability, aesthetics and price compared to competing products and treatment methods. If demand for our products fails to increase, or decreases, our business, including our financial and operating results, may be harmed.

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

Our net revenues remain largely dependent on sales of our Invisalign system of clear aligners and iTero intraoral scanners. Of the two, we expect the Invisalign system will continue to account for the majority of our net revenues, making the widespread acceptance of the Invisalign system by orthodontists, GPs and consumers critical to our success.

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

- we introduce new promotions, change existing promotions, or offer general or volume-based discount programs, product or services bundles, large account sales or consumer rebate programs;
- participation in promotions or programs unexpectedly increases, decreases or changes demand in material ways;
- our geographic, channel or product mix shifts to lower priced products or to products with a higher percentage of deferred revenue;
- we decrease prices 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 volume-based procurement regulations in China; or
- estimates used in the calculation of deferred revenue differ from actual average selling prices.

To stimulate product and services demand, we have a history of offering volume discounts, price reductions and other promotions to targeted customers and consumers and releasing lower priced products. These promotional campaigns and lower

priced products have had, and may in the future have, unexpected and unintended consequences, including reduced gross margins, profitability and average selling prices, net revenues, volume growth, and net income.

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

The dental industry is experiencing immense and rapid digital transformation. While solutions such as our Invisalign system, iTero scanners and CAD/CAM software facilitate this transition, we face competition from companies that also seek to introduce new technologies and products and companies that remain dedicated to conventional products. We may be unable to compete with these competitors or they may render our technology or products obsolete or economically unattractive.

The number and types of competitors are diverse and growing rapidly. The Invisalign system competes primarily with traditional metal wires and brackets and increasingly against clear aligners which are manufactured and distributed by new and existing market entrants, including traditional medical device companies, laboratories, startups and, in some cases, doctors and Dental Support Organizations ("DSOs"). Our competitors also include DTC companies that provide clear aligners using a remote business model requiring little or no in-office care from trained and licensed doctors, and doctors and DSOs who manufacture custom aligners in their offices using 3D printing technology. Large consumer product companies may also start supplying orthodontic products. Orthodontists, GPs and DSOs have and may continue to sample competitive and alternative products and take advantage of competitive promotions and sale opportunities.

Our iTero scanners are also facing increased competition. iTero scanners compete with polyvinyl siloxane ("PVS") impressions and numerous new or existing intraoral scanners. They also compete with traditional bite wing 2D dental x-rays for detecting interproximal caries.

If we are unable to compete effectively with existing products, existing competitors, new market entrants, or respond effectively to new technologies, our business, results of operations and financial condition could be materially impacted.

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

Our success depends on our ability to quickly and profitably develop, manufacture, market, obtain and maintain regulatory approval or clearance of new products and services along with improvements to existing products and services. We cannot assure successful development, sales or acceptance of our new or improved products and services. The extent and rate at which new products or services achieve market acceptance and penetration is a function of many variables, including our ability to:

- successfully predict, timely innovate and develop new technologies, applications and products preferred by customers and consumers that have features and functionality to meet the needs of patients;
- successfully, and in a timely fashion, obtain regulatory approval or clearance of new and improved products or services from government agencies such as the FDA and analogous agencies in other countries;
- cost-effectively and efficiently develop, manufacture, quality test, market, dispose of, and sell new or improved products and services offerings, including localized versions for international markets;
- properly forecast the amount and timing of new or improved product and services demand;
- allocate our research and development funding to products and services with higher growth prospects;
- ensure the compatibility of our technology, services and systems with those of our customers;
- anticipate and rapidly innovate in response to new competitive products and services offerings and technologies;
- differentiate our products and services from our competitors as well as other products and services in our own portfolio and successfully articulate the benefits to our customers;
- manage the impact of nationalism or initiatives encouraging consumer purchases from domestic vendors;
- qualify for third-party reimbursement for procedures involving our products or services;
- offer attractive and competitive service and subscription plans;
- encourage customers to adopt new technologies and provide the needed technical, sales and marketing support to make new product and services launches successful; and
- source and receive quality raw materials or parts from our suppliers.

If we fail to accurately predict the needs and preferences of customers and their patients, or fail to offer viable products or services, we may invest heavily in research and development that does not lead to significant revenues. Even if we successfully innovate and develop new products and product improvements, we may incur substantial costs doing so and our profitability may suffer. Introduction and acceptance of any products and services may take significant time and effort, particularly if they require doctor education and training to understand their benefits or doctors choose to withhold judgment on a product until patients complete their treatments.

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

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

Periodically, we have and may in the future acquire, or make investments in, companies, technologies, or other assets. Alternatively, we may be unable to find suitable investment or acquisition opportunities or be unable to complete investments or acquisitions on favorable terms. If we make investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve desired synergies, and investments or acquisitions we complete could be viewed negatively by our customers, securities analysts and investors. Opposition to acquisitions may lead to negative ratings by analysts or investors, give rise to stockholder objections or result in stockholder activism, any of which could disrupt our operations or harm our stock price. Moreover, to the extent we make strategic investments, the companies in which we invest may fail or we may ultimately own less than a majority of the outstanding shares of the company and be unable to control or have significant influence over critical issues that could harm the value of our investment.

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

- fail to perform proper due diligence and inherit unexpected material issues or assets, including intellectual property ("IP") or other litigation or ongoing investigations, accounting irregularities or compliance liabilities;
- fail to comply with regulations, governmental orders or decrees;
- experience IT security and privacy compliance issues;
- invest in companies that generate net losses or are slow or fail to develop;
- not realize a positive return on investment or determine that our investments have declined in value, necessitating we 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 impede our ability to manage our operations;
- find it difficult to implement and harmonize company-wide financial reporting, forecasting and budgeting, accounting, billing, IT and other systems due to inconsistencies in standards, internal controls, procedures and policies;
- require significant time and resources to effectuate the integration;
- fail to retain key personnel or harm our existing culture or the culture of an acquired entity;

- not realize material portions of the expected synergies and benefits of the investment or acquisition; or
- unsuccessfully evaluate or utilize the acquired technology or acquired company's know-how or fail to successfully integrate the technologies acquired.

Operational Risks

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

Our quarterly and annual operating results have and will continue to fluctuate for a variety of reasons. Some of the factors that have historically, and could in the future, cause our operating results to fluctuate include:

- changes in consumer and doctor demand;
- higher 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 our average selling prices;
- seasonal fluctuations;
- improvements to or changes in our products, capabilities or technologies that replace or shorten the life cycles of legacy products or cause customers to defer or stop purchasing legacy products until new products become available;
- longer customer payment cycles and greater difficulty in accounts receivable collection;
- costs and expenditures, including in connection with new treatment planning and fabrication facilities, the hiring and deployment of personnel and litigation;
- the timing of clear aligner treatment order submission, acceptance, processing and fulfillment, which can cause fluctuations in our backlog; and
- timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows.

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

Conversely, if we overestimate customer demand, we may have excessive staffing, materials, components and finished products, or capacity. If we 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, to secure supplies for production of products, we periodically enter into non-cancelable minimum purchase commitments with vendors, which could impact our ability to adjust inventory for declining demand. If product demand decreases or increases more than forecast, we may be required to purchase or lease additional or larger facilities and additional equipment, or we may be unable to timely fulfill customer demand. Responding to unanticipated changes in demand may take time, lower our gross margin, inhibit sales or harm our reputation.

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

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

We are subject to operating risks, including excess or constrained capacity and pressure on our internal systems, personnel and suppliers. To manage current and anticipated future operations effectively, we must continually implement and improve our operational, financial and management information systems, hire, train, motivate, manage and retain employees, and ensure our suppliers remain diverse and capable of meeting demand for the systems, raw materials, parts and components essential to product manufacturing and delivery. We may fail to balance near-term efforts to meet existing demand with future demand, including adding personnel, creating scalable, secure and robust systems and operations, and automating processes for long term efficiencies. Production of our Invisalign system and iTero scanners could also be limited by capacity constraints due to a variety of factors, including labor shortages, shipping delays, our dependency on third-party vendors for key materials,

parts, components and equipment, and limited production yields. Any such failure could materially impact our business, operations and prospects.

Additionally, we have established treatment planning and manufacturing facilities closer to our international customers to provide better experiences, create efficiencies, and provide redundancy should other facilities become unavailable. If a facility is temporarily, partially or fully shut down, we may be unable to timely fulfill orders, which may negatively impact our financial results, reputation and overall business.

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

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

We have a complex, global iTero scanner installed base of older and newer models. These models are continually updated to add, expand or improve features with new hardware, or to provide repair or replacement parts. We have experienced hardware issues in the past and may in the future, including issues relating to manufacturing, design, quality, or safety, of which we become aware only after products or changes have been introduced into the market. We also have not been and may continue to be unable to ensure that third party components or changes to them will be compatible with, or will not have a negative impact on the functionality of, our iTero scanners. As a result, there have been and may be widespread failures of our iTero scanners or we may experience epidemic failures of our iTero scanners to perform as anticipated. Previously, we have not been and in the future may not be prepared for, or have the infrastructure to, timely and adequately remediate or implement corrective measures for such failures, including due to our dependency on third party providers or suppliers. Consequently, any remediation may be time-consuming and difficult to achieve, which may materially impact our customers and business partners, damage our reputation and result in lost business and revenue opportunities, and could be materially costly.

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

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

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

We are highly dependent on our supply chain, particularly manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our iTero scanners. We maintain single supply relationships for many of these machines and materials. By using single suppliers in limited locations for materials and manufacturing, we are exposed to multiple supply chain vulnerabilities.

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

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

In addition to our direct sales force, we have and expect to continue to use distributors to import, market, sell, service and support our products. Our distribution agreements are generally non-exclusive and terminable by either party with customary notice. If alternative distributors cannot be quickly found and trained in the use, marketing, sales and support of our products and services, our revenues and ability to sell or service our products in key markets could be adversely affected. These distributors may also choose to sell alternative or competing products or services. In addition, we may be held responsible for the actions of these distributors and their employees and agents for compliance with laws and regulations, including fair

competition, bribery and corruption, trade compliance, safety, data privacy and marketing and sales activities. The conduct of these distributors also impacts our reputation and our brand. If our distributors fail to satisfy customers, our reputation and brand loyalty could be harmed. A distributor may also affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if it holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for non-compliance or prevents us from taking control of any such authorization. It may be difficult, expensive, and time-consuming for us to re-establish market access or regulatory compliance.

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

We are dependent on commercial freight carriers, primarily UPS, to deliver our products. If the operations of carriers are disrupted or we fail to mitigate any disruptions, we may be unable to timely deliver products to our customers who may choose alternative products, causing our net revenues and gross margin to decline, possibly materially. Moreover, when fuel costs increase, our freight costs generally do so as well. In addition, we earn an increasingly larger portion of our total revenues from international sales, which carry higher shipping costs that negatively impact our gross margin and results of operations. If freight costs materially increase and we are unable to successfully pass all or significant portions of the increases along to our customers, or we cannot otherwise offset such increases, our gross margin and financial results could be materially affected.

Our success depends on our personnel. If we cannot attract, motivate, train or retain personnel, it may be difficult to achieve our strategic priorities, materially effecting our results of operations.

We are highly dependent on the talent and efforts of our personnel. We strive to retain our personnel by providing competitive compensation and benefits, development opportunities and training, flexible work options, and an inclusive corporate culture. However, competition for highly-skilled personnel is intense, particularly technical and digital talent, and our competitors have and are likely to continue to recruit our personnel. Our compensation and benefit arrangements may not successfully attract new employees, retain or motivate existing employees. In addition, other internal and external factors can impact our ability to hire and retain talent, including insufficient advancement or career opportunities and restrictive immigration policies. The loss of any key personnel, particularly executive management, research and development personnel or sales personnel, could harm our business and prospects and impede the achievement of our research and development, operational or strategic objectives.

We provide significant training to our personnel and our business will be harmed if our training fails to properly prepare them to perform the work required, we are unable to successfully instill technical expertise in new and existing personnel or if our techniques prove unsuccessful or are not cost-effective. Moreover, for certain roles, this training and experience can make key personnel, such as our sales personnel, highly desirable to competitors and lead to increased attrition. It can take up to twelve months or more to train sales representatives to successfully market and sell our products and for them to establish

strong customer relationships. The loss of the services and knowledge of our highly-skilled employees may significantly delay or prevent the achievement of our development and business objectives.

Additionally, seamless leadership transitions for key positions is critical to sustaining our culture and organizational success. If our succession planning is ineffective, it could adversely impact our business. We continue to assess key personnel we believe essential to our long-term success. Moreover, future organizational changes may cause employee attrition rates to increase. If we fail to effectively manage any organizational or strategic changes, our financial condition, results of operations, and reputation, as well as our ability to successfully attract, motivate and retain key employees, may be harmed.

We have adopted a hybrid work schedule in many of our offices, allowing employees to collaborate and connect with others several days each week while providing the option to work remotely other days. This hybrid work approach may create challenges with maintaining our corporate culture, employee satisfaction and hiring, promotion, and retention.

We believe a key to our success has been the culture we have created that emphasizes a shared vision and values focusing on agility, customer success and accountability. We have experienced and may continue to experience in the future, difficulties attracting and retaining employees that meet the qualifications, experience, compliance mindset and values we expect. If we cannot attract and retain personnel that meet our selection criteria or relax our standards, our corporate culture, ability to achieve our strategic objectives, and our compliance with obligations under our internal controls and other requirements may be harmed. This could have a material adverse effect on our results of operations and our ability to maintain market share.

We have employees represented by works councils in certain countries and others that may be or may become eligible to be represented by works councils, trade unions and other employee associations. Labor disputes and work stoppages involving our employees may disrupt our operations and could materially impact our results or operations.

We depend on our marketing activities to deepen our market penetration and raise awareness of our brands and products, which may prove unsuccessful or may become less effective or more costly to maintain in the long term.

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

In addition, various countries prohibit certain types of marketing activities. For example, some countries restrict direct to consumer advertising of medical devices. We have in the past and may again in the future be alleged to violate marketing restrictions and be ordered to stop certain marketing activities or prevented from selling our products. Moreover, competitors do not always follow these restrictions, creating an unfair advantage and making it more difficult and costly to compete.

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

We have been incorporating and continue to work to further incorporate artificial intelligence ("AI") into our products, services and internal operations. Implementation of AI and machine learning technologies may result in legal and regulatory risks, reputational harm or have other adverse consequences to our business.

We have and are continuing to incorporate AI, including machine learning and independent algorithms, in certain of our products, services and internal operations, which is intended to enhance their operation and effectiveness internally and for our customers, suppliers and consumers. AI innovation presents risks and challenges that could impact our business. Our, or vendors', AI algorithms may be flawed. Our datasets or AI training algorithms may be insufficient or contain biased information. Additionally, many countries and regions, including the EU, have proposed new and evolving regulations related to the use of AI and machine learning technologies. The regulations may impose onerous obligations and may require us to unexpectedly rework or reevaluate improvements to be compliant. Use of AI technologies may expose us to an increased risk of regulatory enforcement and litigation. Moreover, some of the AI features involve the processing of personal data and may be subject to laws, policies, legal obligations, and codes of conduct related to privacy and data protection. AI development and deployment practices could subject us to competitive harm, regulatory enforcement, increased cybersecurity risks, reputational harm and legal liability.

Legal, Regulatory and Compliance Risks

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

We currently are and may in the future be subject to antitrust, competition or unfair competition related investigations, enforcement actions or claims by governmental agencies, competitors, consumers, customers, and others which, even if unfounded, could cause us to incur substantial costs, enter into settlements, consents, be subject to judgments, involve negative publicity, and divert management time and attention, which may materially impact our results of operations. Resolving these matters may require us to change our business practices in materially adverse ways. Governments and regulators are actively developing new competition laws and regulations aimed at the technology sector, AI and digital platforms and coordinating activities globally, including in large markets such as the EU, U.S., and China. Government regulatory actions and court decisions may result in fines or hinder our ability to provide certain benefits to our consumers, reducing the attractiveness of our products and the revenue derived from them. These actions and decisions may also hinder our ability to pursue certain mergers, acquisitions, business combinations or other transactions.

We are currently subject to two antitrust actions with jury trials scheduled to begin on May 13, 2024, and January 21, 2025. We believe the plaintiffs' claims are without merit in each of these actions, but we will likely incur costs in connection with these trials and with our defense, and there is a risk that we will be subject to adverse judgments or negative publicity.

Failure to obtain or maintain approvals or comply with regulations regarding our products or services or those of our suppliers could materially harm our sales, result in substantial penalties and fines and cause harm to our reputation.

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

- the storage, transmission and disclosure of personal, financial, and medical information as well as healthcare records;

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

The healthcare and technology markets are also highly regulated and subject to changing political, economic and regulatory influences. Global regulators are expanding and changing regulations and guidance for products, which can limit the potential benefits of products and cause protracted review timelines for new products. Our critical third-party vendors and service providers are similarly subject to various regulations. Our failure or the failure of our suppliers, customers, advertisers and influencers to strictly adhere to clearances or approvals in the labeling, marketing and sales of our products and services could subject us to claims or litigation, including allegations of false or misleading advertising or violations of laws or regulations, which may result in costly investigations, fines, penalties, as well as material judgments, settlements or decrees. We are also subject to complex, new and changing environmental, health and safety regulations. There can be no assurance we will adequately address the business risks associated with the implementation and compliance with such laws and our internal processes and procedures to comply with such laws or that we will be able to take advantage of any resulting business opportunities.

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

We and certain of our third-party vendors must also comply with and adhere to facility registration and product listing requirements for Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Failure to satisfactorily correct an adverse inspection finding or to comply with applicable manufacturing regulations can result in enforcement actions, or we may be required 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 payments to foreign officials for the purpose of obtaining or maintaining business, securing

an advantage and directing business to another. To comply with ABAC laws, regulators require that we maintain accurate books and records and a system of internal accounting controls. Under the FCPA, we may be held liable for corruption by directors, officers, employees, agents, or other strategic or local partners or representatives.

In addition, while we have policies requiring compliance with applicable laws and regulations and we provide significant training to foster compliance, our employees, third parties acting on our behalf and customers may not properly adhere to our policies or applicable laws or regulations, including the use of certain electronic communications and maintaining accurate books and records. If our personnel or the personnel of our agents or suppliers fail to comply with any laws, regulations, policies or procedures, or we fail to audit and enforce compliance, our reputation may be harmed, we may lose customers, revenues, or face regulatory investigations, actions and fines.

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

We retain confidential customer personal and financial, patient health and our own proprietary information and data essential to our business operations. We rely on the effectiveness of our IT systems, our policies and contracts and policies of our third-party vendors and the IT systems of our service providers and other third parties to safeguard the information and data. Additionally, our success depends on our healthcare providers, many of whom are individual or small operations with limited IT experience and inadequate or untested security protocols, to successfully manage data privacy and security requirements. It is critical that the facilities, infrastructure and IT systems on which we depend and the products we develop remain secure and be perceived by the marketplace and our customers as secure. Despite the implementation of security features in our products and security measures in our IT systems, we and our service providers, third-party vendors, and other third parties are targeted by or subject to physical break-ins, computer viruses and other malicious code, unauthorized or fraudulent access, programming errors or other technical malfunctions, hacking or phishing attacks, malware, ransomware, employee error or malfeasance, cybersecurity attacks, and other breaches of IT systems or similar disruptive actions, including

by organized groups and nation-state actors. For example, we have experienced, and may again experience in the future, cybersecurity incidents and unauthorized internal employee exfiltration of company information.

Further, the frequency and sophistication of third-party cybersecurity attacks is increasing. 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 management, and require significant time and resources to address. Legal or regulatory action against us could prevent us from resolving issues quickly or force us to resolve them in unanticipated ways, cause us to incur significant expense and damages, or result in orders forcing us to cease operations or modify our business practices in ways that materially limit or restrict the capabilities of our products and services. Concerns over our privacy practices could adversely affect others' perception of us and deter customers and patients from using our products. In addition, patient care could suffer, and we could be liable if our products or IT systems fail to timely deliver accurate and complete information. We have cybersecurity and other forms of insurance coverage related to a cyber attacks, breaches, and other incidents or security problems. However, damages and claims arising from specific incidents may not be covered, may exceed the amount of any coverage, and do not cover the time and effort we incur investigating and responding to any incidents, which may be material. The costs to eliminate, mitigate or recover from security problems and cybersecurity attacks and incidents could be material and, depending on the nature and extent of the problem and the networks or products impacted, may result in network or systems interruptions, decreased product sales, or data loss that may have a material impact on our operations, net revenues and operating results.

Additionally, our iTero scanners sold to customers globally, strategic business partners or other locations may be independently or collectively the target of cybersecurity incidents or attacks or subject to viruses, bugs, or other similar negative intruders. Due to the large and growing number of these decentralized devices, we may be unable, or not have the capacity, knowledge, or infrastructure, to respond to or remedy a cybersecurity issue in a timely manner, which may cause loss or damage to us, our customers, or strategic business partners or may cause further malfunctions in, or damage to, our servers, databases, systems or products and services, loss or damage of our data, interruption or temporary cessation of our operations, or an overall negative impact to our business or reputation.

We are also subject to federal, state and foreign laws and regulations respecting the security and privacy of patient healthcare information applicable to healthcare providers and their business associates, such as HIPAA, as well as those relating to privacy, data security, content regulation, and consumer protection. We are subject to various national and regional data localization or data residency laws, including U.S. state law, the EU General Data Protection Regulation and analogous laws in China which generally require certain types of data collected within a country be stored and processed only within that country or approved countries. Other countries are considering 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. These laws and regulations are constantly evolving and may be created, interpreted, applied, or amended in ways that adversely affect our business.

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

Our products and services involve an inherent risk of claims concerning their design, materials, manufacture, safety and performance, how they are marketed and advertised in a complex framework of highly regulated domestic and international laws and regulations, how we package, bundle or sell them to individual customers or companies, including hospitals and clinics, and how we train and support doctors, their staffs and patients who 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 our products or services cause injury or are otherwise found unhealthy. If our products are safe but they are promoted for use or used in unintended or unexpected ways or for which we have not obtained clearance ("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 scrutiny of our ESG policies and practices may materially increase our costs, expose us to 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 are and may be required to comply with new, broader, more complex and more costly ESG laws and regulations. Our compliance obligations span all aspects of our business and operations, including product design and development, materials sourcing and

other procurement activities, product packaging, product safety, energy and natural resources usage, facilities design and utilization, recycling and collection, transportation, disposal activities and workers' rights.

Environmental regulations related to greenhouse gases, hazardous materials, sustainability and reduction of waste are expected to have an increasingly larger impact on us or our suppliers. Many U.S. and foreign regulators have or are considering enacting new or additional disclosure requirements or limits on the emissions of greenhouse gases, including carbon dioxide and methane, from power generated using fossil fuels. The effects of greenhouse gas emission limits on power generation are subject to significant uncertainties, including the timing of new requirements, levels of emissions reductions and the scope and types of emissions regulated. Additionally, laws on sustainability and waste reduction are increasing and consumers may demand our products, packaging and operations be more sustainable, affect how we manufacture and package our products, increase our costs and those of our suppliers, and which may result in manufacturing, transportation and supply chain disruptions if clean energy or sustainable alternatives are not readily available in adequate amounts when required. Moreover, alternative clean energy sources, coupled with reduced investments in traditional energy production and infrastructure, may not provide the predictable, reliable, and consistent energy that we, our suppliers and other businesses require.

Additionally, the sourcing and availability of metals used in the manufacture of, or contained in, our products may be affected by laws and regulations governing the use of minerals obtained from certain regions of the world like the Democratic Republic of Congo and adjoining countries. Although we do not believe we source minerals from this region, our expanding geographic operations may increase the risk of purchasing "conflict minerals" and our efforts to identify whether any of our products contain minerals impacted by these laws and regulations may not be adequate or complete. Other restrictions apply to the substances incorporated into our products, including the chemical compounds in our clear aligners, the electronics in our iTero scanners, and the packaging in which they are shipped. These laws are proliferating and new substances subject to restrictions are regularly being added each year. We may be forced to re-design our products or identify new suppliers to maintain our compliance with these laws. Further, these laws and regulations may decrease the number of suppliers capable of supplying our needs, thereby negatively affecting our ability to manufacture products in sufficient quantities at competitive prices, leading customers to potentially choose competitive goods and services.

Meeting our obligations under existing ESG laws and regulations is costly for us and our suppliers, and we expect these regulations and costs to increase materially. Additionally, regulators may perform investigations, inspections and periodically audit our compliance with these laws and regulations, and we cannot be sure our efforts or operations will be compliant. If we fail to comply with any requirements, we could be subject to significant penalties or liabilities and we may be required to implement new and materially more costly processes and procedures. Even if we successfully comply with these laws and regulations, our suppliers may not. We may also suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are complaint. 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 companies' ESG practices continues to grow. If our ESG practices fail to meet investor or other industry stakeholders' frequently evolving expectations and standards, our brand, reputation and employee retention may be harmed, customers and suppliers may be unwilling to do business with us and investors may be unwilling to invest in us. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, comply with or timely report on our ESG efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our reputation, business, financial performance, growth, and stock price may be adversely impacted.

Intellectual Property Risks

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

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

We rely on our portfolio of issued and pending patent applications in the U.S. and other countries to protect a large part of our IP and our competitive position; however, these patents may not prevent third parties from producing competing products similar in design to ours if they are invalidated, held unenforceable, circumvented, or otherwise limited in scope. Furthermore, our foreign patent protections may be more limited in geographic scope than those under U.S. patent and IP laws.

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

choose not to file a foreign patent application if the limited protections provided by a foreign patent do not outweigh the costs to obtain it. Further, third parties may file patents or develop IP strategies that prevent or limit the effectiveness of our patents.

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

Enforcement of our IP rights is time-consuming and costly, and could ultimately prove to be unsuccessful. In certain jurisdictions, enforcement of IP rights is more difficult due to legislation and geopolitical circumstances. As we launch our products in different regions at different times, our products may be acquired and reverse engineered by potential competitors in regions where infringement is more difficult to pursue.

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

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

Extensive litigation over IP rights is common in technologies and industries on which our products and services are based. Litigation, interferences, oppositions, re-exams, inter partes reviews, post grant reviews or other proceedings have been necessary and will likely be needed in the future to determine the validity and scope of certain of our IP rights and those claimed by third parties. These proceedings are used to determine the validity, scope or non-infringement of certain patent rights pertinent to the manufacture, use or sale of our products and the products of competitors. We have been sued for infringement of third parties' patents in the past and are currently defending patent infringement lawsuits and other legal claims. In addition, we periodically receive letters from third parties drawing our attention to their IP rights and there may be other third-party IP rights of which we are presently unaware. As dentistry continues to become more digital, competitors may make defense of our IP more challenging. Asserting or defending these proceedings can be unpredictable, protracted, time-consuming, expensive and distracting to management and technical personnel. Their outcomes may adversely affect our ability to manufacture and market our products, require us to seek licenses for infringing products or technologies or result in the assessment of significant monetary damages. Unfavorable rulings could include monetary damages, injunctions prohibiting us from selling our products, or exclusion orders preventing us from importing our products in one or more countries. Moreover, independent

actions by competitors, customers or others have alleged that our efforts to enforce our IP rights constitute unfair competition or violations of antitrust laws and investigations and additional litigation based on the same or similar claims may be brought in the future. The potential effects on our business operations resulting from litigation, whether or not ultimately determined in our favor or settled by us, are costly and could materially affect our results of operations and reputation.

Financial, Tax and Accounting Risks

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

Under GAAP, we review our goodwill at least annually, or more frequently, if we identify events or circumstances that indicate it is more likely than not that the fair value of a reporting unit has been reduced below its carrying value. We review finite-lived intangible assets and long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the asset (asset group) may not be recoverable. The qualitative analysis performed by management to identify indicators of impairment or the quantitative analysis used to determine fair value requires management to exercise significant judgement in determining appropriate assumptions and estimates, including revenue growth rates, gross and operating margins, discount rates and future cash flows. Management is responsible for continually assessing qualitative factors that could negatively impact the fair value of goodwill and intangible and long-lived assets and if required, assesses the fair value of each to determine if they have become impaired. Consequently, we may be required to record a material charge to earnings our financial statements during the period in which any impairment of goodwill, intangible or long-lived asset group is determined.

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

We prepare our consolidated financial statements in conformity with GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or in the way these policies are interpreted by us or regulators could materially effect 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 affect our stock price.

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

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

A majority of our marketable investments are investment grade, liquid, fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U.S. financial sector. In an unstable credit or economic environment, it is necessary to assess the value of our investments more frequently and we might incur material realized, unrealized or impairment losses associated with these investments. Additionally, bank failures could cause or continue to cause volatility in the credit or capital markets, market-wide liquidity issues, bank-runs and general concern across the global financial industry. These conditions could limit our access to capital or impair the value of assets we hold.

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

We are 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, our legal entity structure or activities performed within our entities, our business operations, in tax laws, regulations and/or rates, to existing accounting pronouncements, interpretations of existing tax laws or regulations, in relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have

differing statutory tax rates, in overall levels of pretax earnings, as well as the settlement of income tax audits and non-deductible goodwill impairments. Furthermore, we may continue to experience variation in our effective tax rate related to excess tax benefits or tax expense on stock-based compensation, particularly in the first quarter of each year when the majority of our equity awards vest.

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

Compliance with tax laws requires significant judgment concerning our worldwide provision for income taxes. Changes in tax laws or changes to how those laws are applied to our business could affect the amount of tax which we are subject to and the manner in which we operate. Specifically, in 2016, the Organization for Economic Cooperation and Development ("OECD") established the Inclusive Framework on Base Erosion and Profit Shifting ("BEPS") to among other things, allocate greater taxing rights to countries where customers are located and establish a global minimum tax rate. After years of evaluating their respective tax laws, many countries have enacted changes, or are committed to enacting changes, which may increase our tax expense in future years. For example, the European Union and other countries have enacted or have committed to enact the OECD/G20 Framework's Pillar Two 15% global minimum tax. If more countries adopt these changes based on the BEPS guidance, our provision for income taxes or operations may be adversely affected.

Moreover, the application of indirect taxes (such as sales and use tax ("SUT"), value-added tax ("VAT"), goods and services tax ("GST"), and other indirect taxes) to our operations is complex and evolving. U.S. states, local and foreign taxing jurisdictions have differing rules and regulations governing differing types of taxes, and these rules and regulations are subject to varying interpretations and exemptions that may change over time. We collect and remit SUT, VAT, GST and other taxes in many jurisdictions and we are routinely subject to audits. We are also routinely audited regarding our tax reporting and remissions by local and national governments, and may also be subject to audits in jurisdictions for which we have not accrued tax liabilities. The positions we take regarding taxes as well as the amounts we collect or remit may be challenged and we may be liable for failing to collect or remit all 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 or may determine that such

taxes should have but have not been paid by us. If we dispute rulings or positions taken by tax authorities, we may incur significant expenses, time and effort to defend our positions.

During the year ended December 31, 2023, the Company received a notice and initial assessment from His Majesty's Revenue and Customs ("HMRC") for unpaid VAT related to certain clear aligner sales made during various periods beginning 2019 through 2023. While we assert that these sales are exempt from VAT, that we have reasonably relied upon statements and guidance by HMRC and that our interpretation of relevant legislation is appropriate, and believe that a potential loss related to unpaid VAT is not probable, it is possible that we may be subject to a loss in connection with unpaid VAT.

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

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

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

- quarterly variations in our results of operations and liquidity or changes in our forecasts and guidance;
- our ability to regain or sustain our historical growth rates;
- changes in recommendations by the investment community or speculation in the press or investment community regarding estimates of our net revenues, operating results or other performance indicators;
- announcements by us or our competitors or new market entrants, including strategic actions, management changes, and material transactions or acquisitions;
- technical factors in the public trading markets for our stock that may produce price movements inconsistent with macro, industry or company-specific fundamentals, including the sentiment of retail investors (as it may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock, fractional share trading, and other technical trading factors or strategies;
- 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, often experience extreme price and volume fluctuations unrelated 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. Securities litigation, including securities class action lawsuits and securities derivative lawsuits, is often brought against an issuer following periods of volatility in the market price of its securities and we have not been exempt from such litigation.

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

We have a history of recurring stock repurchase programs intended to return capital to our investors. Future stock repurchase programs are contingent on a variety of factors, including our financial condition, market conditions, results of operations, business requirements, and our continuing determination that stock repurchases are in the best interests of our stockholders and in compliance with all applicable laws and agreements. There is no assurance that we will continue repurchasing our common stock in the future at historical levels or at all, or that our stock repurchase programs will beneficially impact our stock price. Additionally, effective January 1, 2023, the Inflation Reduction Act imposes a 1% excise tax on our stock repurchases, which will increase our tax liabilities and the cost to retire stock and may impact if and how much stock we choose to repurchase in the future.

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We have implemented a cross-departmental approach to managing cybersecurity risk, which includes seeking input from our employees, management, third-party vendors, the Audit Committee of the Board of Directors (the "Audit Committee"), and the Board of Directors. We devote significant resources to cybersecurity and risk management processes to adapt to the changing cybersecurity landscape and respond to emerging threats in a timely and effective manner. We regularly assess the threat landscape and take a holistic view of cybersecurity risks, with a layered cybersecurity strategy based on prevention, detection and response. To more effectively address cybersecurity threats, we have a dedicated Chief Information Security Officer ("CISO") who is responsible for leading enterprise-wide information security strategy, policy, process, and technology. Our current CISO has 20+ years of information security and risk management experience and holds a Certified Information Systems Security Professional (CISSP) certification. Our CISO regularly briefs our Audit Committee on our cybersecurity and information security program and cybersecurity incidents deemed to pose a risk of a critical business impact or reputational harm. Our cybersecurity risk management program leverages the National Institute of Standards and Technology (NIST) framework, which organizes cybersecurity risks into five categories: identify, protect, detect, respond and recover. Our information security team, comprised of employees with an expertise in cybersecurity and information technology, regularly assess the threat landscape and take a holistic view of cybersecurity risks, with a layered cybersecurity strategy based on prevention, detection, and response.

Our information security program includes, among other things, cybersecurity incident response, vulnerability management, antivirus and malware protection, technology compliance and risk management, encryption, identity and access management, application security, and security monitoring. The program also has an information security awareness program, which includes annual training regarding our acceptable use and information classification and handling policies, regular phishing campaigns complemented by additional employee training as appropriate, and communications and companion trainings to keep our users informed on current events.

The information security program's ultimate goal is preventing cybersecurity incidents to the extent feasible, while simultaneously increasing our system resilience to minimize the business impact should an incident occur. In the event of an identified cybersecurity incident, we have developed a detailed cybersecurity incident response process, which outlines the steps to be followed from incident detection, analysis, containment, eradication, recovery, and notification, including notifying functional areas (e.g. information technology, legal, finance, operations, privacy), as well as senior leadership and the Audit Committee, as appropriate. For critical cybersecurity incidents, processes have been established for our legal team to determine the materiality of each incident.

Our information security team engages third-party services to conduct evaluations of our security controls, including penetration testing and independent audits. Annually, an external

auditor conducts a System and Organization Controls (“SOC”) type 2 audit covering the security principle for systems supporting our products.

Our assessment of risks associated with the use of third-party vendors is part of our overall cybersecurity risk management framework. If a third-party vendor is unable to provide a SOC 1 or SOC 2 report, our information security team takes additional steps to assess their cybersecurity preparedness and our initiation or continued engagement with them. Additionally, third-party vendors are required to include security and privacy addendums to our contracts where applicable and are reassessed periodically as necessary depending on the risk level that has been assigned to the third-party vendor. Our legal team also requires that our third-party vendors report cybersecurity incidents to us so the impact of the incident on us can be assessed.

Our Audit Committee is responsible for reviewing cybersecurity risks and our cybersecurity program. It oversees and reviews our cybersecurity and other information technology risks, controls, policies, and procedures. Our information security team annually performs a cybersecurity enterprise risk assessment and presents the results to management and the Audit Committee. The Audit Committee periodically reports on its review of cybersecurity risks and our cybersecurity program to our Board of Directors. In 2023, our CISO or his team met with the Audit Committee four times to discuss cybersecurity risks and threats.

We have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. Notwithstanding the approach we take to cybersecurity, we may not successfully prevent or mitigate cybersecurity incidents that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be covered or, if covered, fully insured. See Item 1A. “Risk Factors” for a discussion of cybersecurity risks.

Item 2. Properties.

We occupy several leased and owned facilities. As of December 31, 2023, 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
Belen, Heredia, Costa Rica	Own	Office for administrative personnel, treatment personnel, and customer care
La Lima, Cartago, Costa Rica	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.

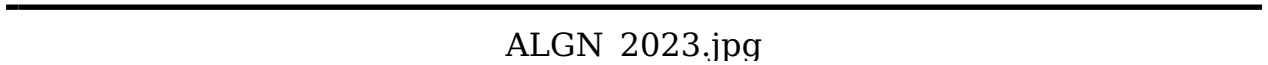
Market Information

Our common stock is traded on the NASDAQ Global Market under the symbol ALGN. As of February 22, 2024, there were approximately 52 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, 2018 to December 31, 2023.



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, 2023:

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, 2023 through October 31, 2023	1,049,538	$ 190.56	1,049,538	$ 750,000,000
November 1, 2023 through November 30, 2023	283,335	$ 206.89	283,335	$ 691,380,496
December 1, 2023 through December 31, 2023	182,183	$ 227.14	182,183	$ 650,000,000
Total	1,515,056		1,515,056	

[1] January 2023 Repurchase Program. In January 2023, we announced that our Board of Directors had authorized a plan to repurchase up to $1,000,000,000 of our common stock. See Note 10 “Common Stock Repurchase Programs” of the Notes to Consolidated Financial Statements for details on the January 2023 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 2023 compared to fiscal 2022 is presented under Results of Operations of this Form 10-K. Discussions regarding our financial condition and results of operations for fiscal 2022 compared to 2021 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, 2022, filed with the SEC on February 27, 2023, 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 focus on four principal pillars for growth: (i) international expansion; (ii) GP dentist treatment; (iii) patient demand; 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 have also diversified our research and development activities throughout Europe, which has created a longer term, more stable environment for consistent hiring, retention and innovation in a variety of high technology sectors. We are in over 100 markets and have 13 fabrication and treatment locations throughout the world.

- 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. We continue to expand our clear aligner customer base by educating new doctors on the benefits of digital dentistry through the Invisalign system. We furthermore demonstrate 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 operational 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. To increase awareness and educate young adults, parents and teens about the benefits of the Invisalign brand, in 2023 we continued to invest in and create campaigns across markets in media platforms such as TikTok, Instagram, YouTube, SnapChat, WeChat, and Douyin. 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 continued our focus on our doctor subscription plan and grew our underpenetrated share of the retainer business through strategic marketing campaigns focused on driving adoption and increasing market share in the U.S., Canada, Iberia and the Nordics.

- 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 about 70% of the

approximately 22 million total annual global orthodontic case starts. We continue to emphasize the benefits of the Invisalign system for teenage and younger patient treatments through education, training and sales and marketing programs. In 2023, we had record shipments to teenage and younger patients. We expect utilization rates to continue 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, and adoption rates for new products and features.

Macroeconomic Challenges and Military Conflict in Ukraine and the Middle East

Our revenues are susceptible to fluctuations caused by macroeconomic conditions, inflation, changes to currency exchange rates, rising interest rates, actual and threatened wars and military actions, threats of or actual recessions, supply chain challenges, market volatility, and other factors, each of which impacts customer confidence, consumer sentiment and demand. Many of these same factors also impact our costs and those of our suppliers through higher raw material prices, transportation costs, labor costs, supply and distribution operations. In 2023, we believe that sales of our products were primarily harmed by macroeconomic conditions that ultimately adversely impacted disposable income and consumer demand. In particular, dental practices and industry research firms reported deteriorating orthodontic trends for the third and fourth quarters of 2023, including decreased patient visits and increased patient appointment cancellations, along with fewer case starts overall, especially among adult patients. The impact of declining demand varied by time and region, making operational results uncertain and difficult to predict.

Additionally, many of our international operations are denominated in currencies other than the U.S. dollar. In 2023, the macroeconomic slowing or contraction resulted in foreign exchange volatility causing the U.S dollar to strengthen against other currencies. This negatively impacted our financial condition and results of operation compared to 2022. Foreign exchange

volatility and the subsequent strengthening or weakening of the U.S dollar against other currencies remains uncertain and unpredictable.

Moreover, military conflicts increase the unpredictability of the volatile macroeconomic conditions. While the military conflict between Russia and Ukraine did not materially impact our 2023 financial condition and results of operations, we expect the conflict will continue to create market uncertainties and dampen consumer sentiment and demand, particularly in Europe.

Similarly, the recent conflict in the Middle East may further exacerbate general and regional macroeconomic instability, particularly if fighting is prolonged, it spreads to other locations, creates shipping and logistical challenges or cost increases, or leads to sanctions or boycotts. Our iTero business is headquartered in Israel and the timing and cost of shipping our products has been impacted. Additionally, we have employees and consultants in Israel that have been called for military service and they may be unavailable for an unknown period of time. The conflict may continue to spread to other areas which may further impact our business. We continue to monitor the potential for violence and military actions that may directly or indirectly impact our personnel, manufacturing, supply chain, and sales.

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 trends and uncertainties, including the macroeconomic conditions, military conflict 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.

For instance, in the first quarter of 2023, we successfully launched the Invisalign Comprehensive 3in3 product. The 3in3 configuration offers doctors Invisalign Comprehensive treatment with a three-year treatment expiration date and three additional clear aligners included prior to the treatment expiration date. We anticipate adoption of the Invisalign Comprehensive 3in3 product will continue to increase in 2024. The 3in3 product allows us to recognize more revenue up front but is offered at a lower price as compared to our traditional Invisalign comprehensive product that has a five-year treatment expiration date with unlimited additional clear aligner prior to the treatment end date.

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, 2023, our business operations reflect the following:

- Revenues of $3,862.3 million, an increase of 3.4% year-over-year;
- Clear Aligner revenues of $3,199.3 million, an increase of 4.1% year-over-year;
  - Americas Clear Aligner case revenues of $1,463.0 million, a decrease of 0.6% year-over-year;
  - International Clear Aligner case revenues of $1,449.5 million, an increase of 7.4% year-over-year;
  - Clear Aligner volume increase of 0.4% year-over-year and Clear Aligner volume increase for teenage patients of 7.8% year-over-year;
- Imaging Systems and CAD/CAM Services revenues of $662.9 million, an increase of 0.1% year-over-year;
- Income from operations of $643.3 million and operating margin of 16.7%;
- Effective tax rate of 30.6%;
- Net income of $445.1 million with diluted net income per share of $5.81;
- Cash, cash equivalents and marketable securities of $980.8 million as of December 31, 2023;
- Operating cash flow of $785.8 million;
- Capital expenditures of $177.7 million, predominantly related to purchases of property, plant and equipment; and
- Number of employees was 21,610 as of December 31, 2023, a decrease of 6.7% year-over-year.

Other Statistical Data and Trends

- As of December 31, 2023, 17 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 2023, total Invisalign cases submitted with a digital scanner in the Americas increased to 95.1%, up from 92.7%* in the fourth quarter of 2022 and international scans increased to 88.1%, up from 86.8% in the fourth quarter of 2022. For the fourth quarter of 2023, 98.0% of Invisalign cases submitted by North American orthodontists were submitted digitally.

- The total utilization rate in 2023 was 19.1 cases per doctor compared to 19.3* cases per doctor in 2022 and 20.9* cases per doctor in 2021. Our utilization rates have declined in 2023 due to the macroeconomic conditions 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 94.5 cases per doctor in 2023 compared to 94.9* cases per doctor in 2022 and 99.7* cases per doctor in 2021 and the utilization rate among our North American GP customers was 14.0 cases per doctor in 2023 compared to 13.9 cases per doctor in 2022 and 14.3 cases per doctor in 2021.

    - International: International doctor utilization rate was 16.3 cases per doctor in 2023 compared to 16.2 cases per doctor in 2022 and 17.5 cases per doctor in 2021.

14597

* 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.

During the third quarter of 2023, we began including Touch Up case revenues in Americas and/or International net revenues that were previously included in Non-Case revenues and have recast business metrics for the periods presented above accordingly.

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.
    - We also offer in the U.S., Canada, and EMEA, a Doctor Subscription Program which is our monthly subscription-based clear aligner program. The program allows doctors the flexibility to order retainers and low-stage “touch-up” clear 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. The low-stage aligners, the Touch up product, are included as a Non-Comprehensive Product.
    - Non-Case products include, but are not limited to, retention products including retention aligners ordered through the Doctor Subscription Program, 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 commerce channels in select markets.
- 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, 2023, 2022 and 2021 are as follows (in millions):

Net Revenues	Year Ended December 31, 2023	2022	Change		Year Ended December 31, 2022	2021	Change	
Clear Aligner revenues:								
Americas	$1,463.0	$1,471.9	$ (9.0)	(0.6)%	$1,471.9	$1,548.8	$ (76.9)	(5.0)%
International	1,449.5	1,349.0	100.5	7.4 %	1,349.0	1,498.7	(149.7)	(10.0)%
Non-case	286.9	251.7	35.2	14.0 %	251.7	199.6	52.1	26.1 %
Total Clear Aligner net revenues	$3,199.3	$3,072.6	$126.7	4.1 %	$3,072.6	$3,247.1	$(174.5)	(5.4)%
Systems and Services net revenues	662.9	662.1	0.9	0.1 %	662.1	705.5	(43.5)	(6.2)%
Total net revenues	$3,862.3	$3,734.6	$127.6	3.4 %	$3,734.6	$3,952.6	$(217.9)	(5.5)%

During 2023, we began including Touch Up case revenues in Americas and/or International net revenues. Touch Up case revenues were previously recorded in Non-case revenues. We have recast the year ended December 31, 2022 and 2021 to reflect this change. Amount and percentage changes are based on recast amounts. 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, 2023, 2022 and 2021 is as follows (in thousands):

	Year Ended December 31,				Year Ended December 31,			
	2023	2022	Change		2022	2021	Change	
Total case volume	2,408.5	2,398.4	10.2	0.4 %	2,398.4	2,559.6	(161.3)	(6.3)%

During 2023, we began including Touch Up case revenues in Americas and/or International net revenues. Touch Up case revenues were previously recorded in Non-case revenues. We have recast the year ended December 31, 2022 and 2021 to reflect this change. Amount and percentage changes are based recast amounts. Certain tables may not sum or recalculate due to rounding.

Total net revenues increased by $127.6 million in 2023 as compared to 2022, primarily due to an increase in Clear Aligner average selling price (“ASP”), an increase in Clear Aligner non-case revenue and higher Systems and Services services mix, partially offset by a decrease in both scanner volumes and ASP’s.

Clear Aligner - Americas

Americas net revenues decreased by $9.0 million in 2023 as compared to 2022, primarily due to a 2.1% decrease in case volumes, resulting in a reduction of net revenues of $31.4 million, partially offset by a $22.4 million increase due to higher ASP. Higher ASP includes price increases which increased net revenues by $68.6 million along with higher additional aligners which increased net revenues by $43.9 million. The increases in ASP were partially offset by higher promotional discounts which decreased net revenues by $44.3 million, a product mix shift to lower priced products which reduced net revenues by $37.6 million and higher sales credits which lowered net revenues $11.5 million.

Clear Aligner - International

International net revenues increased by $100.5 million in 2023 as compared to 2022 due to a 3.5% increase in case volumes, resulting in an increase of net revenues by $46.9 million, and higher ASP increasing net revenues by $53.6 million. Higher ASP was largely due to higher additional aligners increasing net revenues by $100.8 million and price increases on most products which increased net revenues by $96.9 million. The increases in ASP were partially offset by a product mix shift to lower priced products reducing net revenues by $68.2 million, higher promotional discounts which reduced net revenues by $52.5 million, and unfavorable foreign exchange rates which decreased net revenues by $27.2 million.

Clear Aligner - Non-Case

Non-case net revenues increased by $35.2 million in 2023 compared to 2022 mainly due to increased volume of Vivera retainers across all regions which includes retention aligners ordered through our Doctor Subscription Program.

Systems and Services

Systems and Services net revenues decreased by $0.9 million in 2023 as compared to 2022 primarily due to a lower number of scanners sold which lowered net revenues by $26.1 million and lower scanner ASP which reduced net revenues by $23.9 million. The decrease in scanner net revenues was mostly offset by higher service revenues of $31.8 million and other revenues which increased $19.1 million primarily due to revenue from sales of certified pre-owned scanners, CAD/CAM software, and scanner rentals.

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

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Clear Aligner						
Cost of net revenues	$ 911.3	$ 844.4	$ 66.9	$ 844.4	$ 772.7	$ 71.7
% of net segment revenues	28.5 %	27.5 %		27.5 %	23.8 %	
Gross profit	$ 2,288.0	$ 2,228.2	$ 59.9	$ 2,228.2	$ 2,474.4	$ (246.2)
Gross margin %	71.5 %	72.5 %		72.5 %	76.2 %	
Systems and Services						
Cost of net revenues	$ 244.1	$ 256.4	$ (12.3)	$ 256.4	$ 244.5	$ 11.9
% of net segment revenues	36.8 %	38.7 %		38.7 %	34.7 %	
Gross profit	$ 418.8	$ 405.6	$ 13.2	$ 405.6	$ 461.0	$ (55.4)
Gross margin %	63.2 %	61.3 %		61.3 %	65.3 %	
Total cost of net revenues	$ 1,155.4	$ 1,100.9	$ 54.5	$ 1,100.9	$ 1,017.2	$ 83.6
% of net revenues	29.9 %	29.5 %		29.5 %	25.7 %	
Gross profit	$ 2,706.9	$ 2,633.8	$ 73.1	$ 2,633.8	$ 2,935.4	$ (301.6)
Gross margin %	70.1 %	70.5 %		70.5 %	74.3 %	

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 2023 as compared to 2022 primarily due to a increased manufacturing spend offset by higher ASP.

Systems and Services

The gross margin percentage increased in 2023 as compared to 2022 primarily due to lower purchase price variance and higher service revenue mix, partially offset by lower ASP.

Selling, general and administrative (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Selling, general and administrative	$1,703.4	$1,674.5	$ 28.9	$1,674.5	$1,708.6	$ (34.2)
% of net revenues	44.1 %	44.8 %		44.8 %	43.2 %	

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 increased in 2023 compared to 2022 primarily due to higher employee costs, including higher salaries expense, fringe benefits, stock-based compensation and bonus, offset by lower advertising and marketing and outside service provider costs.

Research and development (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Research and development	$ 346.8	$ 305.3	$ 41.6	$ 305.3	$ 250.3	$ 54.9
% of net revenues	9.0 %	8.2 %		8.2 %	6.3 %	

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 2023 compared to 2022 primarily due to higher employee costs, including higher salaries expense, fringe benefits, stock-based compensation and bonus as we continue to focus our investments in innovation and research.

Restructuring and other charges (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Restructuring and other charges	$ 13.3	$ 11.5	$ 1.9	$ 11.5	$ —	$ 11.5
% of net revenues	0.3 %	0.3 %		0.3 %	— %	

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

Restructuring and other charges incurred during 2023 was primarily related to post employment benefits, including employee severance.

Income from operations (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Clear Aligner						
Income from operations	$1,182.3	$1,134.4	$ 47.8	$1,134.4	$1,325.9	$ (191.4)
Operating margin %	37.0 %	36.9 %		36.9 %	40.8 %	
Systems and Services						
Income from operations	$ 191.4	$ 179.8	$ 11.6	$ 179.8	$ 259.1	$ (79.4)
Operating margin %	28.9 %	27.2 %		27.2 %	36.7 %	
Total income from operations [1]	$ 643.3	$ 642.6	$ 0.7	$ 642.6	$ 976.4	$ (333.8)
Operating margin %	16.7 %	17.2 %		17.2 %	24.7 %	

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 remained relatively flat in 2023 compared to 2022 primarily due to a decrease in gross margin which was offset by operating leverage.

Systems and Services

Operating margin percentage increased in 2023 compared to 2022 primarily due to higher gross margin.

Interest income (in millions):

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Interest income	$ 17.3	$ 5.4	$ 11.9	$ 5.4	$ 3.1	$ 2.3
% of net revenues	0.4 %	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 2023 compared to 2022 primarily due to higher interest rates during 2023.

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

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Other income (expense), net	$ (19.4)	$ (48.9)	$ 29.5	$ (48.9)	$ 32.9	$ (81.8)
% of net revenues	(0.5)%	(1.3)%		(1.3)%	0.8 %	

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 2023 compared to 2022 primarily due to the favorable impact of foreign exchange rates offset slightly by losses in investments in private companies.

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

	Year Ended December 31,			Year Ended December 31,		
	2023	2022	Change	2022	2021	Change
Provision for (benefit from) income taxes	$ 196.2	$ 237.5	$(41.3)	$ 237.5	$ 240.4	$ (2.9)
Effective tax rates	30.6 %	39.6 %		39.6 %	23.7 %	

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

The decrease in our effective tax rate for the year ended December 31, 2023 compared to the same period in 2022 is primarily attributable to the application of newly issued tax guidance, including IRS Notice 2023-55 and a change in our jurisdictional mix of income.

Liquidity and Capital Resources

Liquidity and Trends

As of December 31, 2023 and 2022, we had the following cash and cash equivalents and short-term and long-term marketable securities (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents	$ 937,438	$ 942,050
Marketable securities, short-term	35,304	57,534
Marketable securities, long-term	8,022	41,978
Total	$ 980,764	$ 1,041,562

As of December 31, 2023 and 2022, approximately $784.7 million and $653.7 million, respectively, of cash, cash equivalents and marketable securities were held by our foreign subsidiaries. We intend to reinvest our foreign subsidiary earnings indefinitely outside of the U.S. and do not expect to incur significant additional costs upon repatriation of these foreign earnings. We generate sufficient domestic operating cash flow and have access to $300.0 million under our 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.

Our material cash requirements as of December 31, 2023 are as below:

- Our purchase commitments consist primarily of open purchase orders for goods and services, including manufacturing inventory, supplies and services, sales and marketing, research and development services and technological services, issued in the normal course of business. Our purchase commitments totaled $1,234.5 million. We anticipate a majority, an estimated $861.5 million, will be payable within the next 12 months. These purchase commitments exclude capital expenditures.

- We expect our investments in capital expenditures to be approximately $100.0 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 $153.5 million, which includes $13.3 million for leases that have not yet commenced as of December 31, 2023. Refer to Note 4 “Leases” of the Notes to Consolidated Financial Statements for details on the lease payments.

- We have approximately $650.0 million available for repurchases of our common stock under the stock repurchase program authorized by our Board of Directors in January 2023 (“January 2023 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. Beginning in fiscal year 2023 our stock repurchases, net of certain issuances, were subject to a 1% excise tax. This excise tax is not expected to have a material impact on our liquidity or capital resources.

- On January 2, 2024 we completed the acquisition of the remaining interest in privately held Cubicure GmbH for total purchase consideration of approximately $87 million. We paid approximately $79 million in cash, which represents the total purchase consideration less credit for our previously owned interest.

- As of December 31, 2023, we had no material off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material impact on our liquidity or capital resources.

Sources and Use of Cash

The following table summarizes our Consolidated Statements of Cash Flows for the year ended December 31, 2023, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Net cash provided by (used in):			
Operating activities	$ 785,776	$ 568,732	$ 1,172,544
Investing activities	(195,943)	(213,316)	(563,430)
Financing activities	(598,340)	(501,686)	(458,332)
Effects of foreign exchange rate changes on cash, cash equivalents, and restricted cash	4,671	(11,514)	(12,117)
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (3,836)	$ (157,784)	$ 138,665

Operating Activities

For the year ended December 31, 2023, cash flows from operations of $785.8 million resulted primarily from our net income of approximately $445.1 million as well as the following:

Significant adjustments to net income

- Stock-based compensation of $154.0 million related to equity awards granted to employees and directors; and

- Depreciation and amortization of $142.4 million related to our investments in property, plant and equipment and intangible assets.

Significant changes in working capital

- Inflow of $46.3 million, net from accrued and other long-term liabilities primarily due to higher incentive accruals for 2023, as well as timing of payments of other activities;
- Inflow of $86.7 million, net from deferred revenues due to the deferral of revenue on shipments;
- Inflow of $30.2 million, net from inventories primarily due to lower purchases of materials used in manufacturing; and
- Outflow of $104.6 million, net from accounts receivable due to timing of collections and increased revenues.

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;
- Depreciation and amortization of $125.8 million related to our investments in property, plant and equipment and intangible assets; and

Significant changes in working capital

- Inflow of $241.9 million, net from deferred revenues due to the deferral of revenue on shipments over the period as well as timing of revenue recognition;
- Outflow of $130.1 million, net from inventories primarily due to lower shipment volumes over the period in addition to our efforts to manage stock at appropriate levels as required; and
- Outflow of $121.9 million, net from accrued and other long-term liabilities primarily due to the payment of our 2021 corporate bonus as well as timing payment of other activities.

Investing Activities

Net cash used in investing activities was $195.9 million for the year ended December 31, 2023 which primarily consisted of purchases of property, plant and equipment of $177.7 million which included a building acquisition for $24.5 million, an investment in the equity of a privately held company of $77.0 million and purchases of marketable securities of $2.9 million, partially offset by sales and maturities of marketable securities of $61.4 million.

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.

Financing Activities

Net cash used in financing activities was $598.3 million for the year ended December 31, 2023 which consisted of payments to repurchase shares of our common stock of $602.4 million and payroll taxes paid for equity awards through share withholdings of $22.6 million, which were partially offset by $26.6 million of proceeds from the issuance of common stock.

Net cash used in financing activities was $501.7 million for the year ended December 31, 2022 which consisted of payments to repurchase shares of our common stock 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.

Critical Accounting 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 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.

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 historical prices, changing trends and market conditions, 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 consideration 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. For CAD/CAM services, we estimate the SSP of each element, including the initial software license and maintenance and support, using data such as historical prices.

Unfulfilled Performance Obligations for Clear Aligners and Scanners

Our unfulfilled performance obligations, including deferred revenues and backlog, and the estimated revenues expected to be recognized in the future related to these performance obligations are $1,578.3 million and $1,515.4 million as of December 31, 2023 and 2022, respectively. This includes performance obligations from the Clear Aligner reportable segment, primarily the shipment of additional aligners, which are fulfilled over six

months to five years. This also includes performance obligations from our Systems and Services reportable 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.

Impairment of Goodwill and Finite-Lived Intangible Assets

Goodwill

We evaluate goodwill for impairment at least annually on November 30th or more frequently if indicators of impairment are identified between annual testing dates. Goodwill is tested for impairment between annual testing dates when events or circumstances indicate that the fair value of a reporting unit has been reduced below its carrying value. When an indicator of impairment is identified we perform a quantitative impairment assessment in which we determine the fair value of a reporting unit and compare it to the carrying value of the respective reporting unit. We generally determine the fair value of a reporting unit via a discounted cash flow analysis and allocate the net assets of the Company to each reporting unit to determine carrying value. We will record an impairment charge when our quantitative impairment analysis indicates that the carrying value of a reporting unit exceeds its fair value. Both the determination of fair value and carrying value of a reporting unit require management to exercise significant judgement related to operating assumptions and estimates and allocation methodologies.

Finite-Lived Intangible Assets

Finite-lived intangible assets are reviewed for impairment when events or circumstances indicate that the carrying value of an asset (asset group) may not be recoverable. When an impairment indicator is identified, we perform a recoverability test, in which the estimated, undiscounted future cash flows expected to result from the use and eventual disposition of the asset (asset group) are compared to the carrying value of the asset (asset group). When our recoverability test results in undiscounted cash flows more than carrying value, no impairment is recorded. However, when our recoverability test results in undiscounted cash flows that are less than carrying value, we determine the fair value of the asset (asset group) and reduce the carrying amount of the asset (asset group), through an impairment charge, to its fair value. The process of identifying impairment indicators, preparing an undiscounted cash flow and determining the fair value of the asset (asset group) require management to exercise significant judgement related to various assumptions and estimates.

If we were to have impairments to goodwill or finite-lived intangible assets, it could adversely affect our operating results. During the years ended 2023 and 2022, we did not have any impairment charges related to our goodwill or finite-lived 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 for a discussion of recent accounting pronouncements, including the

expected dates of adoption and estimated effects, if any, 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, various military conflicts and consumer confidence. 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 and 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 or we may suffer losses in principal if forced to sell securities which have declined in market value due. As of December 31, 2023, we had approximately $43.3 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, 2023, 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, British Pound, 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.

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

	Page
Report of Management on Internal Control over Financial Reporting	53
Report of Independent Registered Public Accounting Firm (PCAOB ID 238)	54
Consolidated Statements of Operations for the year ended December 31, 2023, 2022 and 2021	56
Consolidated Statements of Comprehensive Income for the year ended December 31, 2023, 2022 and 2021	57
Consolidated Balance Sheets as of December 31, 2023 and 2022	58
Consolidated Statements of Stockholders' Equity for the year ended December 31, 2023, 2022 and 2021	59
Consolidated Statements of Cash Flows for the year ended December 31, 2023, 2022 and 2021	60
Notes to Consolidated Financial Statements	61

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, 2023. 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, 2023, 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, 2023 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 28, 2024

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Executive Vice President, Global Finance

February 28, 2024

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, 2023 and 2022, 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, 2023, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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, 2023, 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 $3.2 billion from its Clear Aligner segment for the year ended December 31, 2023. 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 28, 2024

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,		
	2023	**2022**	**2021**
Net revenues	$ 3,862,260	$ 3,734,635	$ 3,952,584
Cost of net revenues	1,155,397	1,100,860	1,017,229
Gross profit	2,706,863	2,633,775	2,935,355
Operating expenses:			
Selling, general and administrative	1,703,379	1,674,469	1,708,640
Research and development	346,830	305,258	250,315
Restructuring and other charges	13,316	11,453	—
Total operating expenses	2,063,525	1,991,180	1,958,955
Income from operations	643,338	642,595	976,400
Interest income and other income (expense), net:			
Interest income	17,258	5,367	3,103
Other income (expense), net	(19,392)	(48,905)	32,920
Total interest income and other income (expense), net	(2,134)	(43,538)	36,023
Net income before provision for income taxes	641,204	599,057	1,012,423
Provision for income taxes	196,151	237,484	240,403
Net income	$ 445,053	$ 361,573	$ 772,020
Net income per share:			
Basic	$ 5.82	$ 4.62	$ 9.78
Diluted	$ 5.81	$ 4.61	$ 9.69
Shares used in computing net income per share:			
Basic	76,426	78,190	78,917
Diluted	76,568	78,420	79,670

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,		
	2023	**2022**	**2021**
Net income	$ 445,053	$ 361,573	$ 772,020
Other comprehensive income (loss):			
Change in foreign currency translation adjustment, net of tax	28,419	(11,480)	(38,680)
Change in unrealized gains (losses) on investments, net of tax	3,033	(3,130)	(495)
Other comprehensive income (loss)	31,452	(14,610)	(39,175)
Comprehensive income	$ 476,505	$ 346,963	$ 732,845

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,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 937,438	$ 942,050
Marketable securities, short-term	35,304	57,534
Accounts receivable, net of allowance for doubtful accounts of $14,893 and $10,343, respectively	903,424	859,685
Inventories	296,902	338,752
Prepaid expenses and other current assets	273,550	226,370
Total current assets	2,446,618	2,424,391
Marketable securities, long-term	8,022	41,978
Property, plant and equipment, net	1,290,863	1,231,855
Operating lease right-of-use assets, net	117,999	118,880
Goodwill	419,530	407,551
Intangible assets, net	82,118	95,720
Deferred tax assets	1,590,045	1,571,746
Other assets	128,682	55,826
Total assets	$ 6,083,877	$ 5,947,947
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 113,125	$ 127,870
Accrued liabilities	525,780	454,374
Deferred revenues	1,427,706	1,343,643
Total current liabilities	2,066,611	1,925,887
Income tax payable	116,744	124,393
Operating lease liabilities	96,968	100,334
Other long-term liabilities	173,065	195,975
Total liabilities	2,453,388	2,346,589
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; 75,075 and 77,267 issued and outstanding, respectively)	7	8
Additional paid-in capital	1,162,140	1,044,946
Accumulated other comprehensive income (loss), net	21,168	(10,284)
Retained earnings	2,447,174	2,566,688
Total stockholders' equity	3,630,489	3,601,358
Total liabilities and stockholders' equity	$ 6,083,877	$ 5,947,947

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					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss), Net	Retained Earnings	Total
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 [1]	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 [1]	305	—	26,149	—	—	26,149
Tax withholdings						

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,		
	2023	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$445,053	$ 361,573	$ 772,020
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred taxes	(18,642)	(39,495)	15,455
Depreciation and amortization	142,401	125,793	108,729
Stock-based compensation	154,026	133,367	114,336
Non-cash operating lease cost	33,107	30,520	26,807
Impairments on equity investments	4,990	—	—
Arbitration award gain	—	—	(43,403)
Other non-cash operating activities	32,733	41,288	24,363
Changes in assets and liabilities, net of effects of acquisitions:			
Accounts receivable	(104,614)	21,549	(262,066)
Inventories	30,169	(130,097)	(112,450)
Prepaid expenses and other assets	(51,013)	(65,514)	(124,626)
Accounts payable	(7,703)	(36,523)	19,747
Accrued and other long-term liabilities	46,327	(121,942)	158,543
Long-term income tax payable	(7,772)	6,327	12,449
Deferred revenues	86,714	241,886	462,640
Net cash provided by operating activities	785,776	568,732	1,172,544
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisitions, net of cash acquired	—	(12,304)	(8,002)
Purchase of property, plant and equipment	(177,716)	(291,900)	(401,098)
Purchase of marketable securities	(2,910)	(28,002)	(200,928)
Proceeds from maturities of marketable securities	55,170	23,785	498
Proceeds from sales of marketable securities	6,234	97,316	3,114
Repayment on unsecured promissory note	—	—	4,594
Proceeds from arbitration award	—	—	43,403
Purchase of equity investments	(76,999)	—	—
Other investing activities	278	(2,211)	(5,011)
Net cash used in investing activities	(195,943)	(213,316)	(563,430)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	26,595	26,149	25,623
Common stock repurchases	(592,360)	(435,036)	(375,038)
Activity for equity forward contracts related to accelerated stock repurchase agreements, net	(10,000)	(40,000)	—
Payroll taxes paid upon the vesting of equity awards	(22,575)	(52,799)	(108,917)
Net cash used in financing activities	(598,340)	(501,686)	(458,332)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	4,671	(11,514)	(12,117)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(3,836)	(157,784)	138,665
Cash, cash equivalents, and restricted cash at beginning of year	942,355	1,100,139	961,474

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

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES

NOTES TO 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, consumers, orthodontists, 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 accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, ("GAAP") and 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 GAAP requires management to make estimates and assumptions that affect the amounts reported in our 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, plant and equipment, goodwill, income taxes, contingent liabilities, deferred revenues, 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.

In September 2023, we completed an assessment of the useful lives of certain manufacturing equipment used in cutting, forming, assembling and scanning. We adjusted the estimated useful life from ten (10) years to thirteen (13) years. This change in accounting estimate was effective beginning September 2023. These updated useful lives were applied to applicable assets in service as of the date of change and will be applied prospectively as assets are placed in service. Based on the carrying amount of the assets recorded in our property, plant and equipment, net balance prior to the change, the effect of this change in estimate for fiscal year 2023 was a reduction in depreciation expense of approximately $5.4 million and an increase in net income of $3.7 million, or $0.05 per share basic and diluted, for the year ended December 31, 2023.

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. 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 cash 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

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 balance consists 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 marketable 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 collectability 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 assessment of whether we are the primary beneficiary of a VIE require management to exercise significant judgement and utilize assumptions. 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 as an investment in equity securities. We have elected to account for all investments in equity securities in accordance with the measurement alternative. Under the measurement alternative, we record

the value of our investments in equity securities at cost, minus impairment, if any. Additionally, we adjust the carrying value of our investments equity securities to fair value for observable transactions for identical or similar investments of the same issuer.

On April 24, 2023, we entered into a Subscription Agreement (the "Subscription Agreement") with Heartland Dental Holding Corporation (“Heartland”) who is an affiliate of KKR Core Holding Company LLC, which is an investment vehicle managed or advised by, or otherwise affiliated with, Kohlberg Kravis Roberts & Co. L.P. Heartland is a dental support organization (“DSO”) that provides nonclinical administrative and support services to supported dental professional corporations (“PCs”). Pursuant to the Subscription Agreement we acquired less than a 5% equity interest through the purchase of Class A Common Stock for $75 million. In connection with the Subscription Agreement, we entered into a Stockholders’ Agreement, by and among us, Heartland Dental Topco, LLC (“Topco”) and funds and accounts managed by affiliates of KKR & Co. Inc. (“KKR”), and a Side Letter, by and among us, Heartland, Topco and KKR (the "Side Letter"). Subject to certain restrictions set forth in the Side Letter, we agreed to provisions applicable to Heartland’s stockholders, including certain drag-along and voting obligations. We are not the primary beneficiary of nor are we able to exercise significant influence over Heartland. As such, we are accounting for our investment in Heartland as an investment in equity securities.

Similar to our other investments in equity securities, Heartland is accounted for under the measurement alternative. Based on review of our investment in Heartland, we determined that no adjustments to the carrying value were necessary; therefore, it is properly reflected on our Consolidated Balance Sheet in other assets at $75 million.

Investments in equity securities are reported on our Consolidated Balance Sheet as other assets. 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 investments in equity securities, exclusive of Heartland, were not material as of December 31, 2023 or 2022 and the associated adjustments to the carrying values of the investments were not material during the year ended December 31, 2023, 2022 and 2021.

Our investments in privately held companies in which we can exercise significant influence are accounted for as equity method investments. We have elected to account for our equity method investments under the fair value option. The carrying value of our equity method investments are reported on our Consolidated Balance Sheet as other assets and are not material as of December 31, 2023 or 2022.

On September 6, 2023, we entered into a definitive agreement to acquire privately held Cubicure GmbH (“Cubicure”). The purchase price for the transaction will be approximately $87 million subject to customary closing adjustments and adjustments for Align’s existing ownership of capital stock of Cubicure. The acquisition closed on January 2, 2024. Refer to Note 17 “Subsequent Events" of the Notes to Consolidated Financial Statements for further details.

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 of the subsidiary 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 to change in foreign currency translation adjustment, net of tax in our Consolidated Statements of Comprehensive Income. 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. Foreign currency remeasurement gains and losses that are derived from monetary assets and liabilities stated in a currency other than the international subsidiaries functional currency are included in other income (expense), net. For the year ended December 31, 2023, 2022 and 2021, we had foreign currency translation net gains (losses) of $(7.0) million, $(43.8) million and $(13.3) 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, particularly in prior years, have been impacted by the COVID-19 pandemic.

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 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 and giving consideration to various factors including the aging of the receivables and a customers' expected ability to pay. For specific customer accounts receivable balances, we consider known disputes and past 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, net balance at December 31, 2023 or 2022 nor net revenues for the year ended December 31, 2023, 2022 or 2021.

For the year ended December 31, 2023 and 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 financial assets 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 factoring arrangements was $51.2 million and $37.0 million during the year ended December 31, 2023, and 2022, respectively. Factoring fees incurred on the sales of accounts receivable were recorded in other income (expense), net in our Consolidated Statements 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. Depreciation expense is 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 are not ready for their intended use and have not yet been placed in service. 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 or contains 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. A ROU asset and lease liability is recognized on the lease commencement date. The lease liability is determined 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. The ROU asset consists of the initial lease liability adjusted for lease incentives received and any initial direct costs incurred. The lease term

represents the noncancellable period of the lease and may include options to extend 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 ROU asset and lease liability balances. The short-term portion of our lease liabilities is recorded in accrued liabilities on our Consolidated Balance Sheets.

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 determining the fair value of 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

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

Finite-Lived Intangible Assets

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

Impairment of Goodwill and Long-Lived Assets and Finite-Lived Intangible Assets

Goodwill

We evaluate goodwill for impairment at least annually on November 30th or more frequently if indicators of impairment are identified between annual testing dates.

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 has been reduced below its carrying amount. In performing this 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 not more likely than not that the fair value of the reporting unit is less than its carrying value, no further testing is performed; however, if we conclude otherwise, then we will perform a 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 exceeds its fair value, an impairment loss would be recorded in our Consolidated Statements of Operations for the amount of the excess. Management is required to exercise significant judgement when identifying the relevant assumptions and estimates used in determining the fair value and carrying value of our reporting units.

Long-Lived Assets and Finite-Lived Intangible Assets

We evaluate long-lived assets (including ROU assets) and finite-lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (asset group) may not be recoverable. Factors we consider important which could trigger a quantitative impairment test include but are not limited to significant negative industry or economic trends, significant adverse changes in our competitive environment and a significant loss of customers. If an impairment indicator is identified, we perform a quantitative impairment analysis in which we compare the carrying value of an asset (asset group) to the future undiscounted cash flows the asset (asset group) is expected to generate. An asset (asset group) is considered impaired if its carrying amount exceeds the undiscounted cash flows. If an asset (asset group) is deemed to be impaired, the impairment to be recognized is calculated as the amount by which the carrying amount of the asset (asset group)

exceeds its fair value. Our estimates of future cash flows attributable to our assets (asset groups) require significant judgment based on our historical and anticipated results and are subject to many assumptions.

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. Capitalized internally developed software costs were not material as of December 31, 2023 or 2022.

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 intended because it complies with agreed-upon specifications; therefore, our warranties are not treated as a separate revenue performance obligation in accordance with the revenue standard but rather are accounted for as guarantees.

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 product failure rates as well as current information on replacement cost.

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 an additional fee. Sales of extended warranties are accounted for as a separate performance obligation and recorded as revenue.

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 reportable 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 historical prices, changing trends and market conditions, 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 Phase 1, Invisalign First Comprehensive Phase 2, Invisalign Adult, Invisalign Standard, 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. 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 consideration 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 capitalized costs to obtain contracts were $25.1 million and $27.4 million as of December 31, 2023 and 2022, respectively, and are included in other assets in our Consolidated Balance Sheets. We

recognized amortization on our costs to obtain a contract of $12.5 million, $20.8 million, and $17.0 million during the year ended December 31, 2023, 2022, and 2021, 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, and the estimated revenues expected to be recognized in the future related to these performance obligations are $1,578.3 million and $1,515.4 million as of December 31, 2023 and 2022, respectively. This includes performance obligations from the Clear Aligner reportable segment, primarily the shipment of additional aligners, which are fulfilled over six months to five years. This also includes performance obligations from our Systems and Services reportable 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 satisfied with payment terms generally varying from net 30 to net 180 days. Contract liabilities are recorded as deferred revenue, which is generated based upon the timing of invoices and recognition patterns, not payments. If the revenue recognition exceeds the billing, the excess amount is considered an unbilled receivable or 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 Litigation

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.

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.

Research and Development

Research and development costs are expensed as incurred and include 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, 2023, 2022 and 2021, we incurred advertising costs of $201.2 million, $222.0 million and $325.6 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 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.

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 of 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

On November 27, 2023, the FASB issued ASU 2023-07, “Improvements to Reportable Segment Disclosures.” The amendments in this update improve reportable segment disclosure requirements, primarily through enhanced disclosures about

significant segment expenses. For public business entities, the provisions of ASU 2023-07 are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Companies must apply the guidance retrospectively to all prior periods presented in the financial statements. The Company is evaluating the effect of this pronouncement on its annual consolidated financial statements.

On December 14, 2023, the FASB issued ASU 2023-09, “Improvements to Income Tax Disclosures.” The amendments in this ASU require a public entity to disclose in tabular format, using both percentages and reporting currency amounts, specific categories in the rate reconciliation and to provide additional information for reconciling items that meet a quantitative threshold. The amendments in this ASU also require taxes paid (net of refunds received) to be disaggregated by federal, state, and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. For public business entities, the provisions of ASU 2023-09 are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is evaluating the effect of this pronouncement on its annual consolidated financial statements.

Note 2. Financial Instruments

Cash, Cash Equivalents and Marketable Securities

The following tables summarize our cash and cash equivalents, and marketable securities recorded in our Consolidated Balance Sheets as of December 31, 2023 and 2022 (in thousands):

					Reported as:		
December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and cash equivalents	Marketable securities, short-term	Marketable securities, long-term
Cash	$887,682	$ —	$ —	$887,682	$887,682	$ —	$ —
Money market funds	49,756	—	—	49,756	49,756	—	—
Corporate bonds	31,943	5	(676)	31,272	—	28,704	2,568
U.S. government treasury bonds	4,855	—	(99)	4,756	—	—	4,756
Asset-backed securities	1,416	2	(1)	1,417	—	719	698
Municipal bonds	702	—	(2)	700	—	700	—
U.S. government agency bonds	5,215	—	(34)	5,181	—	5,181	—
Total	$981,569	$ 7	$ (812)	$980,764	$937,438	$ 35,304	$ 8,022

December 31, 2022	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	$ 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

The following tables summarizes the fair value of our available-for-sale marketable securities classified by contractual maturity as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	2022
Due in 1 year or less	$ 34,617	$ 51,037
Due in 1 year through 5 years	8,709	48,475
Total	$ 43,326	$ 99,512

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, 2023 and 2022 are primarily due to changes in interest rates and credit spreads.

The following tables summarize the gross unrealized losses as of December 31, 2023 and 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, 2023					
	Less than 12 months		12 Months or Greater		Total	
December 31, 2023	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	$ —	$ —	$ 27,939	$ (676)	$ 27,939	$ (676)
U.S. government treasury bonds	2,044	(11)	2,712	(88)	4,756	(99)
Asset-backed securities	1,018	(1)	83	—	1,101	(1)
Municipal bonds	—	—	700	(2)	700	(2)
U.S. government agency bonds	4,003	(11)	1,178	(23)	5,181	(34)
Total	$ 7,065	$ (23)	$ 32,612	$ (789)	$ 39,677	$ (812)

	As of December 31, 2022					
	Less than 12 months		12 Months or 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)

Fair Value Measurements

The following tables summarize our financial assets measured at fair value and categorized by fair value hierarchy as of December 31, 2023 and 2022 (in thousands):

Description	Balance as of December 31, 2023	Level 1	Level 2
Cash equivalents:			
Money market funds	$ 49,756	$ 49,756	$ —
Short-term investments:			
Corporate bonds	28,704	—	28,704
Municipal bonds	700	—	700
U.S. government agency bonds	5,181	—	5,181
Asset-backed securities	719	—	719
Long-term investments:			
U.S. government treasury bonds	4,756	—	4,756
Corporate bonds	2,568	—	2,568
Asset-backed securities	698	—	698
	$ 93,082	$ 49,756	$ 43,326

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

We had no financial assets that were categorized as level 3 in the fair value hierarchy for the year ended December 31, 2023 or 2022.

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 assets and liabilities. These forward contracts are classified within Level 2 of the fair value hierarchy. As a result of the settlement of foreign currency forward contracts, we recognized a net loss of $15.9 million during the year ended December 31, 2023. The net gain recognized during the year ended 2022 was not material and we recognized a net gain of $18.8 million during the year ended December 31, 2021. As of December 31, 2023 and 2022, the fair value of foreign exchange forward contracts outstanding was not material.

The following tables present the gross notional value of all our foreign exchange forward contracts outstanding as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€337,780	$ 373,705
Canadian Dollar	C$108,900	82,166
Polish Zloty	PLN276,900	70,393
British Pound	£45,590	58,005
Chinese Yuan	¥244,500	34,361
Swiss Franc	CHF28,600	34,132
Japanese Yen	¥3,577,000	25,347
Israeli Shekel	ILS78,700	21,800
Brazilian Real	R$80,500	16,563
Mexican Peso	M$230,000	13,593
New Zealand Dollar	NZ$6,600	4,161
Australian Dollar	A$4,300	2,921
New Taiwan Dollar	NT$89,000	2,919
Czech Koruna	Kč60,200	2,687
Korean Won	₩2,200,000	1,709
		$ 744,462

	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

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 145,492	$ 172,758
Work in progress	91,259	96,558
Finished goods	60,151	69,436
Total inventories	$ 296,902	$ 338,752

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

	December 31,	
	2023	2022
Value added tax receivables	$ 143,728	$ 140,484
Prepaid expenses	52,487	69,124
Other current assets	77,335	16,762
Total prepaid expenses and other current assets	$ 273,550	$ 226,370

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

		December 31,	
	Generally Used Estimated Useful Life	2023	2022
Clinical and manufacturing equipment	Up to 13 years	$ 703,805	$ 583,776
Building	20 years	517,554	466,003
Leasehold improvements	Lease term [1]	62,216	64,238
Computer software and hardware	3 years	125,633	120,544
Land	—	63,875	58,885
Furniture, fixtures and other	2-5 years	122,820	102,933
Construction in progress	—	245,722	285,202
Total		1,841,625	1,681,581
Less: Accumulated depreciation and impairment charges		(550,762)	(449,726)
Total property, plant and equipment, net		$1,290,863	$1,231,855

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

Depreciation was $126.0 million, $109.8 million and $92.1 million for the year ended December 31, 2023, 2022 and 2021, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued payroll and benefits	$ 220,862	$ 149,508
Accrued expenses	71,109	64,341
Accrued income taxes	38,103	74,323
Accrued sales and marketing expenses	34,035	36,407
Current operating lease liabilities	29,651	26,574
Accrued property, plant and equipment	23,618	19,922
Other accrued liabilities	108,402	83,299
Total accrued liabilities	$ 525,780	$ 454,374

Accrued warranty as of December 31, 2023 and 2022, which is included in the “Other accrued liabilities” category in the accrued liabilities table above, consists of the following activity (in thousands):

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
Charged to cost of net revenues		18,248
Actual warranty expenditures		(13,695)
Accrued warranty as of December 31, 2023	$	22,426

Deferred revenues consist of the following (in thousands):

	December 31,	
	2023	2022
Deferred revenues - current	$ 1,427,706	$ 1,343,643
Deferred revenues - long-term [1]	138,000	160,662

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

During the year ended December 31, 2023 and 2022, we recognized $3,862.3 million and $3,734.6 million of net revenues, respectively, of which $732.4 million and $635.3 million was included in the deferred revenues balance at December 31, 2022 and December 31, 2021, 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	**2023**	**2022**	**2021**
Operating lease cost [1]	$ 44,614	$ 37,919	$ 33,241
Variable lease cost [2]	16,013	22,084	11,134
Total lease cost	$ 60,627	$ 60,003	$ 44,375

[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	**2023**	**2022**
Weighted average remaining lease term (in years)	6.2	7.2
Weighted average discount rate	3.7 %	3.5 %

As of December 31, 2023, the future payments related to our operating lease liabilities are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases
2024	$ 33,838
2025	28,381
2026	22,449
2027	16,933
2028	12,746
Thereafter	25,901
Total lease payments	140,248
Less: Imputed interest	(13,629)
Total lease liabilities	$ 126,619

As of December 31, 2023, we had additional leases that have not yet commenced with future lease payments of $13.3 million. These leases will commence during 2024 with non-cancelable lease terms of two to five 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,	
	2023	2022
Scanners under operating leases, gross	$ 27,145	$ 22,914
Less: accumulated depreciation	(9,815)	(3,919)
Scanners under operating leases, net	$ 17,330	$ 18,995

As of December 31, 2023, the future lease payments due to us are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases
2024	$ 22,737
2025	18,170
2026	8,908
Total lease payments	$ 49,815

For the year ended December 31, 2023 and 2022, operating lease income was $16.6 million and $12.3 million, respectively and for the year ended December 31, 2021,

operating lease income was not material. Operating lease income is recorded in net revenues in our Consolidated Statements of Operations.

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, 2023 and 2022, categorized by reportable segment, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
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
Foreign currency translation adjustments	1,606	10,373	11,979
Balance as of December 31, 2023	$ 111,086	$ 308,444	$ 419,530

We completed our annual goodwill impairment assessments in 2023 and 2022 and determined there were no impairments.

Finite-Lived Intangible Assets

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of December 31, 2023	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2023
Existing technology	10	$ 112,051	$ (45,331)	$ (4,328)	$ 62,392
Customer relationships	10	21,500	(8,063)	—	13,437
Trademarks and tradenames	10	16,600	(7,605)	(4,122)	4,873
Patents	8	6,511	(6,082)	—	429
		$ 156,662	$ (67,081)	$ (8,450)	81,131
Foreign currency translation adjustments					987
Total intangible assets, net [1]					$ 82,118

[1] Also includes $34.3 million of fully amortized intangible assets related to customer relationships.

	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.

For the year ended December 31, 2023 and 2022, we did not identify any impairment triggering events that would indicate that the carrying value of our finite-lived intangible assets was not recoverable.

The total estimated annual future amortization expense for these acquired intangible assets as of December 31, 2023 is as follows (in thousands):

Fiscal Year	Amortization
2024	$ 15,335
2025	14,959
2026	14,353
2027	11,992
2028	10,890
Thereafter	13,602
Total	$ 81,131

Amortization expense was $16.4 million, $16.0 million and $16.6 million for the year ended December 31, 2023, 2022 and 2021, 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, 2023, 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.

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 treble monetary damages, interest, costs, attorneys' fees, 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. On December 18, 2023, the court certified a class of persons or entities that purchased Invisalign directly from Align between January 1, 2019 and March 31, 2022. We filed a petition with the Ninth Circuit seeking to appeal the certification ruling. The court denied Plaintiffs' motion to certify a class of purchasers of scanners. On February 21, 2024, the court granted Align's motion for summary judgment on all claims brought by the plaintiffs.

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 treble monetary damages, interest, costs, attorneys' fees, and injunctive relief relating to our alleged market activities in alleged clear aligner and intraoral scanner markets based on Section 2 of the Sherman Act. Plaintiffs have filed several amended complaints adding new plaintiffs, various state law claims, and allegations based on Section 1 of the Sherman Act. On November 29, 2023, the court certified a class of indirect purchasers of Invisalign between July 1, 2018 and December 31, 2023 and a class of indirect purchasers of Invisalign seeking injunctive relief. We filed a petition with the Ninth Circuit seeking to appeal this ruling under Rule 23(f) of the Federal Rules of Civil Procedure. On February 21, 2024, the court granted Align's motion for summary judgment on the claims related to Section 2 allegations. A jury trial is scheduled to begin in this matter on January 21, 2025 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 denied SDC's allegations in the counterclaims.

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 of $63 million in damages.

On May 18, 2023, the arbitrator issued a final award on SDC's second counterclaim, finding that Align did not breach the Supply Agreement. The final award subsumed the interim award on our claims and SDC's first counterclaim and concluded the Supply Agreement arbitration proceedings.

On March 6, 2023, Align filed a petition to confirm the arbitrator's interim award in the Superior Court for Santa Clara County.

On May 30, 2023, Align filed a petition to confirm the final award in the Superior Court of Santa Clara County. On August 21, 2023, the Superior Court issued an order confirming the Interim and Final Awards. On September 8, 2023, the Superior Court entered judgment in Align's favor for $63 million in damages.

On September 29, 2023, SDC and certain affiliates filed bankruptcy petitions under chapter 11 of title 11 of the United States Code in the United States Bankruptcy Court for the

Southern District of Texas. On January 26, 2024, SDC's bankruptcy cases were converted from cases under chapter 11 of the Bankruptcy Code to cases under chapter 7 of the Bankruptcy Code. In conjunction therewith, Allison D. Byman was appointed as the chapter 7 trustee in SDC's bankruptcy cases. The extent to which Align will be able to collect any or all of its $63 million judgment through SDC's bankruptcy proceedings is unknown.

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

Tax Matter

During the quarter ended September 30, 2023, the Company received a notice and initial assessment, in the amount of approximately $27 million, from His Majesty's Revenue and Customs ("HMRC") for unpaid value added tax ("VAT") related to certain clear aligner sales made during the period of June 2022 through May 2023. We are required to pay this initial

assessment prior to contesting or litigating the assessment in administrative and judicial proceedings. The Company has historically asserted and continues to assert that doctor prescribed clear aligners sold by dentists for the orthodontic treatment of patient malocclusions are exempt from VAT, that the Company has reasonably relied upon statements and guidance by HMRC and that the Company's interpretation of United Kingdom legislation is appropriate. However, it is not possible at this stage to accurately evaluate the likelihood of an unfavorable outcome of any legal challenges brought by the Company against HMRC disputing this initial assessment and any assessments for other past periods, if any. Accordingly, the Company has determined that a potential loss related to unpaid VAT is not probable. As such, we have not recorded a contingent loss for the initial assessment in our Condensed Consolidated Statements of Operations for the year ended December 31, 2023. The Company acknowledges that this matter poses risks of litigation and the ultimate resolution of this matter could result in an unfavorable ruling, which consequently could lead to a significant loss to the Company. As of December 31, 2023, if an unfavorable ruling is issued, we estimate a potential exposure up to approximately $100 million, excluding interest and penalties.

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, 2023, 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 Company's Board of Directors. We have not historically 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, 2023, the 2005 Incentive Plan, as amended, has a total reserve of 32,168,895 shares for issuance of which 4,796,559 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

Stock-based compensation related to our stock-based awards and employee stock purchase plan for the year ended December 31, 2023, 2022 and 2021 is as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Cost of net revenues	$ 7,462	$ 6,438	$ 5,633
Selling, general and administrative	115,992	103,134	90,659
Research and development	30,572	23,795	18,044
Total stock-based compensation	$ 154,026	$ 133,367	$ 114,336

The income tax benefit related to stock-based compensation was $17.1 million, $14.9 million and $13.8 million for the year ended December 31, 2023, 2022 and 2021, 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, 2023 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, 2022	489	$ 427.23		
Granted	509	316.16		
Vested and released	(201)	376.41		
Forfeited	(61)	386.66		
Unvested as of December 31, 2023	736	$ 367.63	1.4	$ 201,789

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 fiscal year 2023 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 fiscal year 2023. This amount will fluctuate based on the fair market value of our stock. During 2023, of the 201,358 shares vested and released, 61,267 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 140,091 shares.

The total fair value of RSUs vested as of their respective vesting dates during 2023, 2022 and 2021 was $63.0 million, $93.7 million and $158.8 million, respectively. The weighted average grant date fair value of RSUs granted during 2023, 2022 and 2021 was $316.16, $469.12 and $600.10, respectively. As of December 31, 2023, we expect to recognize $174.3 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 2.6 years.

Market 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 MSU activity for the year ended December 31, 2023:

	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, 2022	144	$ 725.73		
Granted	82	629.53		
Vested and released	(25)	392.67		
Forfeited	(43)	423.87		
Unvested as of December 31, 2023	158	$ 811.06	1.4	$ 43,197

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 2023 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 2023. This amount will fluctuate based on the fair

market value of our stock. During 2023, of the 24,578 shares vested and released, 10,480 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 14,098 shares.

The total fair value of MSUs vested as of their respective vesting dates during 2023, 2022 and 2021 was $7.8 million, $64.0 million and $135.6 million, respectively. As of December 31, 2023, we expect to recognize $47.5 million of total unamortized compensation costs, net of estimated forfeitures, related to MSUs over a weighted average period of 1.4 years.

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,		
	2023	2022	2021
Expected term (in years)	3.0	3.0	3.0
Expected volatility	59.1 %	53.8 %	56.3 %
Risk-free interest rate	4.3 %	1.7 %	0.2 %
Expected dividends	—	—	—
Weighted average fair value per share at grant date	$ 629.53	$ 915.22	$ 1,102.09

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 (grant date) 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,		
	2023	2022	2021
Number of shares issued (in thousands)	114	86	131
Weighted average price	$ 234.19	$ 305.24	$ 195.44

As of December 31, 2023, 1,995,453 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,		
	2023	2022	2021
Expected term (in years)	1.2	1.5	1.1
Expected volatility	56.4 %	50.2 %	52.7 %
Risk-free interest rate	4.9 %	1.8 %	0.1 %
Expected dividends	—	—	—
Weighted average fair value at grant date	$ 132.94	$ 159.44	$ 246.84

We recognized stock-based compensation related to our employee stock purchase plan of $20.5 million, $23.5 million and $12.2 million for the year ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we expect to recognize $6.8 million of total unamortized compensation costs related to future employee stock purchases over a weighted average period of 0.6 years.

Note 10. Common Stock Repurchase Programs

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, 2023, the authorization under the May 2021 Repurchase program was completed. In January 2023, our Board of Directors authorized a new plan to repurchase to $1.0 billion of our common stock ("January 2023 Repurchase Program"). As of December 31, 2023, we have $650.0 million available for repurchases under the January 2023 Repurchase Program.

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 each ASR, 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 for the year ended December 31, 2023 and 2022:

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
Q2 2022	May 2021	$ 200.0	Q2 2022	756,502	$ 264.37
Q4 2022	May 2021	$ 200.0	Q1 2023	984,714	$ 203.10
Q1 2023	May 2021	$ 250.0	Q1 2023	805,908	$ 310.21
Q4 2023	January 2023	$ 250.0	N/A[1]	1,049,538	$ 190.56

[1] As of December 31, 2023, this ASR contract was open. Approximately 20% or $50 million of the Amount Paid was recorded as an equity forward contract within "Additional paid-in capital" in our Statement of Stockholders Equity. The Average price per share in the table is based on $200 million and 1.05 million shares initially delivered. On January 30, 2024 this ASR contract was settled and an additional 36,796 shares were delivered and retired. The average purchase price per share for the completed contract was $230.13 per share.

Open Market Common Stock Repurchases

During the year ended December 31, 2023, we repurchased on the open market approximately 0.5 million shares of our common stock at an average price of $214.81 per share, including commissions and fees, for an aggregate purchase price of approximately $100.0 million.

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 $9.5 million, $10.0 million and $8.5 million to the 401(k) plan during the year ended December 31, 2023, 2022 and 2021, respectively. We also have defined contribution retirement plans outside of the U.S. to which we contributed $55.1 million, $54.5 million and $42.3 million during the year ended December 31, 2023, 2022 and 2021, respectively.

Note 12. Income Taxes

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

	Year Ended December 31,		
	2023	2022	2021
Domestic	$ 315,643	$ 268,097	$ 378,478
Foreign	325,561	330,960	633,945
Net income before provision for (benefit from) income taxes	$ 641,204	$ 599,057	$ 1,012,423

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

	Year Ended December 31,		
	2023	2022	2021
Federal			
Current	$ 134,332	$ 188,050	$ 157,383
Deferred	(16,805)	(55,579)	(25,598)
	117,527	132,471	131,785
State			
Current	28,535	34,621	28,365
Deferred	(3,157)	(12,265)	(5,860)
	25,378	22,356	22,505
Foreign			
Current	51,306	56,537	42,681
Deferred	1,940	26,120	43,432
	53,246	82,657	86,113
Provision for (benefit from) income taxes	$ 196,151	$ 237,484	$ 240,403

The differences between income taxes using the federal statutory income tax rate for the year ended December 31, 2023, 2022 and 2021 and our effective tax rates are as follows:

	Year Ended December 31,		
	2023	2022	2021
U.S. federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State income taxes, net of federal tax benefit	2.9	3.7	2.2
U.S. tax on foreign earnings	3.7	5.6	2.5
Impact of differences in foreign tax rates	1.4	3.3	(2.0)
Stock-based compensation	3.0	2.1	(0.3)
Settlement on audits	0.1	1.9	—
Change in valuation allowance	(1.3)	1.7	1.1
Other items not individually material	(0.2)	0.3	(0.8)
Effective tax rate	30.6 %	39.6 %	23.7 %

We intend to reinvest our foreign subsidiary earnings indefinitely outside of the U.S. and do not expect to incur significant additional costs upon repatriation of these foreign earnings.

As of December 31, 2023 and 2022, the significant components of our deferred tax assets and liabilities are (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss and capital loss carryforwards	$ 1,389	$ 15,380
Reserves and accruals	62,891	32,759
Stock-based compensation	25,054	19,469
Deferred revenue	142,082	117,039
Capitalized research & development	41,505	54,293
Amortizable tax basis in intangibles	1,325,236	1,350,434
Other	13,228	16,645
Deferred tax assets before valuation allowance	1,611,385	1,606,019
Valuation allowance	(14,991)	(23,286)
Total deferred tax assets	1,596,394	1,582,733
Deferred tax liabilities:		
Depreciation and amortization	7,814	11,407
Acquisition-related intangibles	25,097	26,008
Other	3,570	3,438
Total deferred tax liabilities	36,481	40,853
Net deferred tax assets	1,559,913	1,541,880

The available positive evidence at December 31, 2023 included historical operating profits and a projection of future income sufficient to realize most of our remaining deferred tax assets. As of December 31, 2023, it was considered more likely than not that our deferred tax assets would be realized with the exception of certain interest expense carryovers, capital loss carryovers and unrealized translation losses as we are unable to forecast sufficient future profits to realize these deferred tax assets. The total valuation allowance as of December 31, 2023 was $15.0 million. During the year ended December 31, 2023, the valuation allowance decreased by $8.3 million primarily due to the deferred tax assets on certain interest expense, net operating loss carryovers, and unrealized translation losses from our German subsidiaries.

As of December 31, 2023, we have foreign net operating loss carryforwards of approximately $3.7 million, attributed mainly to losses in China, Russia, and Germany. The losses in Germany can be carried forward indefinitely. The operating loss carryforwards in China and Russia, if not utilized, will expire beginning 2028 and 2033, respectively.

The changes in the balance of gross unrecognized tax benefits, which exclude interest and penalties, for the year ended December 31, 2023, 2022 and 2021, are as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Gross unrecognized tax benefits at January 1,	$ 141,560	$ 63,295	$ 46,320
Increases related to tax positions taken during the current year	8,616	84,249	27,710
Increases related to tax positions taken during a prior year	5,647	15,411	5,471
Decreases related to tax positions taken during a prior year	(533)	(2,647)	(5,804)
Decreases related to expiration of statute of limitations	(3,654)	(4,582)	(8,986)
Decreases related to settlement with tax authorities	(2,464)	(14,166)	(1,416)
Gross unrecognized tax benefits at December 31,	$ 149,172	$ 141,560	$ 63,295

The total amount of gross unrecognized tax benefits as of December 31, 2023 was $149.2 million, of which $140.0 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 2019, respectively. With few exceptions, we are no longer subject to examination by other foreign tax authorities for years before 2016.

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, 2023, 2022 and 2021 as well as accrued as of December 31, 2023 and 2022 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,		
	2023	2022	2021
Numerator:			
Net income	$ 445,053	$ 361,573	$ 772,020
Denominator:			
Weighted average common shares outstanding, basic	76,426	78,190	78,917
Dilutive effect of potential common stock	142	230	753
Total shares, diluted	76,568	78,420	79,670
Net income per share, basic	$ 5.82	$ 4.62	$ 9.78
Net income per share, diluted	$ 5.81	$ 4.61	$ 9.69
Anti-dilutive potential common shares [1]	293	320	1

[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,		
	2023	2022	2021
Taxes paid	$ 294,569	$ 231,884	$ 203,309
Non-cash investing and financing activities:			
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	$ 32,280	$ 35,767	$ 64,135
Final settlement of prior year stock repurchase forward contract	$ 40,000	$ —	$ —
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 33,714	$ 31,015	$ 29,769
Right-of-use assets obtained in exchange for lease obligations:			
Operating leases	$ 27,901	$ 34,144	$ 68,463

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 reportable segment. Certain operating expenses are not directly attributable to a reportable segment and must be allocated. Each allocation is measured differently based on the nature of the cost being allocated. Certain other operating expense are not specifically allocated to segment income from operations and 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 reportable 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,		
	2023	**2022**	**2021**
Net revenues			
Clear Aligner	$ 3,199,329	$ 3,072,585	$ 3,247,080
Systems and Services	662,931	662,050	705,504
Total net revenues	$ 3,862,260	$ 3,734,635	$ 3,952,584
Gross profit			
Clear Aligner	$ 2,288,038	$ 2,228,170	$ 2,474,373
Systems and Services	418,825	405,605	460,982
Total gross profit	$ 2,706,863	$ 2,633,775	$ 2,935,355
Income from operations			
Clear Aligner	$ 1,182,257	$ 1,134,420	$ 1,325,866
Systems and Services	191,355	179,765	259,127
Unallocated corporate expenses	(730,274)	(671,590)	(608,593)
Total income from operations	$ 643,338	$ 642,595	$ 976,400
Stock-based compensation			
Clear Aligner	$ 13,963	$ 14,816	$ 10,648
Systems and Services	1,293	994	705
Unallocated corporate expenses	138,770	117,557	102,983
Total stock-based compensation	$ 154,026	$ 133,367	$ 114,336
Depreciation and amortization			
Clear Aligner	$ 64,781	$ 57,888	$ 50,723
Systems and Services	31,518	28,300	21,581
Unallocated corporate expenses	46,102	39,605	36,425
Total depreciation and amortization	$ 142,401	$ 125,793	$ 108,729

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,		
	2023	2022	2021
Total segment income from operations	$ 1,373,612	$ 1,314,185	$ 1,584,993
Unallocated corporate expenses	(730,274)	(671,590)	(608,593)
Total income from operations	643,338	642,595	976,400
Interest income	17,258	5,367	3,103
Other income (expense), net	(19,392)	(48,905)	32,920
Net income before provision for (benefit from) income taxes	$ 641,204	$ 599,057	$ 1,012,423

Our Chief Operating Decision Maker does not regularly review total assets at the reportable segment level; however, we have provided geographical information related to our long-lived assets below.

Geographical Information

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

	Year Ended December 31,		
	2023	2022	2021
Net revenues [1]:			
U.S.	$ 1,665,925	$ 1,660,045	$ 1,724,296
Switzerland	1,168,320	1,216,094	1,353,229
Other International	1,028,015	858,496	875,059
Total net revenues	$ 3,862,260	$ 3,734,635	$ 3,952,584

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

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,	
	2023	2022
Long-lived assets [1]:		
Switzerland	$ 575,432	$ 532,921
U.S.	210,275	214,804
Other International	623,155	603,010
Total long-lived assets	$ 1,408,862	$ 1,350,735

[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 2023, we initiated a restructuring plan to increase efficiencies across the organization which is expected to be completed in the first half of 2024. We incurred approximately $14.0 million in restructuring expenses, of which $0.7 million was recorded in Cost of net revenues and $13.3 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
Balance as of December 31, 2021	$ —	$ —	$ —
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
Restructuring charges	13,989	—	13,989
Cash payments	(12,606)	—	(12,606)
Balance as of December 31, 2023 [1]	$ 5,299	$ —	$ 5,299

[1] Included in “Accrued liabilities” within our Consolidated Balance Sheets.

Note 17. Subsequent Events

Cubicure GmbH Acquisition

The Company had a pre-existing ownership interest of approximately nine percent in privately-held Cubicure GmbH (“Cubicure”), a pioneer in direct 3D printing solutions for polymer additive manufacturing that develops, produces, and distributes innovative materials, equipment, and processes for novel 3D printing solutions. On January 2, 2024, we acquired the remaining ninety-one percent of Cubicure’s outstanding equity interest for approximately $87 million subject to final closing adjustments and adjustments for Align’s existing ownership of capital stock of Cubicure. The purchase price was funded with cash on hand. The acquisition of Cubicure will support and scale our strategic innovation roadmap and strengthen the Align

Digital Platform. Cubicure will also extend and scale Align's printing, materials, and manufacturing capabilities for our 3D printed product portfolio.

We are currently evaluating the purchase price allocation. It is not practicable to disclose the preliminary purchase price allocation, given the short period of time between the acquisition date and the issuance of these consolidated financial statements.

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, 2023 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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the fiscal quarter ended December 31, 2023, no director or officer, as defined in Rule 16a-1(f) of the Exchange Act, adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Regulation S-K Item 408.

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 Responsibilities and Oversight - Compensation and Human Capital Committee Interlocks and Insider Participation” and “Compensation and Human Capital 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 of Regulation S-K is incorporated by reference to the Proxy Statement under the sections captioned “Security Ownership of Certain Beneficial Owners and Management”.

Equity Compensation Plan Information

The following table provides information as of December 31, 2023 about our common stock that may be issued upon the awards granted to employees, consultants or members of our Board of Directors under all existing equity compensation plans, including the 2005 Incentive Plan and the Employee Stock Purchase Plan (“ESPP”), each as amended, and certain individual arrangements (Refer to Note 9 "Stockholders’ Equity” of the Notes to Consolidated Financial Statements for a description of our equity compensation plans).

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units (a)	Weighted average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	898,838 [1]	$ —	7,241,323 [2, 3]
Equity compensation plans not approved by security holders	—	—	—
Total	898,838	$ —	7,241,323

[1] Includes 741,185 RSUs and 157,653 MSUs at 100% of target

[2] Includes 1,995,453 shares available for issuance under our ESPP. We are unable to ascertain with specificity the number of securities to be issued upon exercise of outstanding rights or the weighted average exercise price of outstanding rights under the ESPP.

[3] Includes additional 449,311 of potentially issuable MSUs above target if performance targets are achieved at maximum payout of 250% (in addition to the reserve for one and nine-tenths (1 9/10) shares for every one (1) issuable share against the authorized share reserve)

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 Structure and Independence,” 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:

Report of Independent Registered Public Accounting Firm	54
Consolidated Statements of Operations for the year ended December 31, 2023, 2022 and 2021	56
Consolidated Statements of Comprehensive Income for the year ended December 31, 2023, 2022 and 2021	57
Consolidated Balance Sheets as of December 31, 2023 and 2022	58
Consolidated Statements of Stockholders' Equity for the year ended December 31, 2023, 2022 and 2021	59
Consolidated Statements of Cash Flows for the year ended December 31, 2023, 2022 and 2021	60
Notes to Consolidated Financial Statements	61

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, 2023, 2022 and 2021

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, 2021	$ 10,239	$ 2,814	$ (3,808)	$ 9,245
Year Ended December 31, 2022	$ 9,245	$ 4,102	$ (3,004)	$ 10,343
Year Ended December 31, 2023	$ 10,343	$ 8,002	$ (3,452)	$ 14,893
Valuation allowance for deferred tax assets:				
Year Ended December 31, 2021	$ 1,325	$ 11,613	$ —	$ 12,938
Year Ended December 31, 2022	$ 12,938	$ 10,348	$ —	$ 23,286
Year Ended December 31, 2023	$ 23,286	$ (8,295)	$ —	$ 14,991

(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	
3.1B	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	10-Q	8/4/2023	3.1B	
3.2	Amended and Restated Bylaws of registrant	8-K	1/17/2024	3.1	
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 and restated May 2023)	8-K	5/18/2023	10.1	
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 Restricted Stock Unit Agreement under Registrant's 2005 Incentive Plan (CEO Form)	10-Q	5/5/2023	10.1	
10.8†	Form of Restricted Stock Unit Agreement under Registrant's 2005 Incentive Plan (Executive Officer Form for officers appointed after September 2016)	10-Q	5/5/2023	10.2	
10.9†	Form of Restricted Stock Unit Agreement under Registrant's 2005 Incentive Plan (Executive Officer Form for officers appointed prior to	10-Q	5/5/2023	10.3	

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
10.17†	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	
10.18†	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	
10.19†	Amended and Restated Chief Executive Officer Employment Agreement between Align Technology, Inc. and Joseph Hogan	10-Q	5/1/2015	10.30	
10.20†	Employment Agreement between registrant and John F. Morici (Chief Financial Officer)	10-Q	11/8/2016	10.2	
10.21†	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	
10.22	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	
10.23	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	
10.24	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-K	2/27/2023	10.18	
10.25	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-K	2/27/2023	10.19	
10.26	Fixed Dollar Accelerated Share Repurchase Transaction between Citibank, N.A and Align Technology, Inc. dated October 26, 2023				*
10.27	Subscription Agreement, dated as of April 24, 2023 between Align	10-Q	8/4/23	10.1	

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
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)				*

** Portions of the exhibit, marked by brackets and asterisks [***], have been omitted becau
omitted information is not material and (i) would likely cause competitive harm to the re
if publicly disclosed or (ii) is information that the registrant treats as private or confident

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

t 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 28, 2024**

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 28, 2024
/S/ JOHN F. MORICI **John F. Morici**	Chief Financial Officer and Executive Vice President, Global Finance (Principal Financial Officer and Principal Accounting Officer)	February 28, 2024
/S/ KEVIN T. CONROY **Kevin T. Conroy**	Director	February 28, 2024
/S/ KEVIN J. DALLAS **Kevin J. Dallas**	Director	February 28, 2024
/S/ JOSEPH LACOB **Joseph Lacob**	Director	February 28, 2024
/S/ C. RAYMOND LARKIN, JR. **C. Raymond Larkin, Jr.**	Director	February 28, 2024
/S/ GEORGE J. MORROW **George J. Morrow**	Director	February 28, 2024
/S/ ANNE M. MYONG **Anne M. Myong**	Director	February 28, 2024
/S/ MOJDEH POUL **Mojdeh Poul**	Director	February 28, 2024
/S/ ANDREA L. SAIA **Andrea L. Saia**	Director	February 28, 2024
/S/ SUSAN E. SIEGEL **Susan E. Siegel**	Director	February 28, 2024