

**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, 2024  
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**  
(State or other jurisdiction of  
incorporation or organization)

**94-3267295**  
(I.R.S. Employer  
Identification No.)

**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
<b>Common Stock, \$0.0001 par value</b>	<b>ALGN</b>	<b>The Nasdaq Stock Market LLC (Nasdaq Global Select Market)</b>

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 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 Exchange 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 Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$12.9 billion as of June 28, 2024 based on the closing sale price of the registrant's common stock on the Nasdaq Global Select Market on such date. Shares held by persons who may be deemed affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On February 20, 2025, 73,597,648 shares of the registrant's common stock were outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement relating to its 2025 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The registrant's definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

**ALIGN TECHNOLOGY, INC.**  
**FORM 10-K**  
**For the Year Ended December 31, 2024**  
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*Invisalign, Align, the Invisalign logo, ClinCheck, Invisalign Assist, Invisalign Teen, Invisalign First, Invisalign Go, the Invisalign sonic logo, Vivera, SmartForce, SmartTrack, SmartStage, SmileView, iTero, iTero Element, iTero Lumina, Orthocad, exocad, Align Digital Platform, Invisalign Smile Architect, iTero exocad Connector and exocad Dental CAD, among others, are trademarks and/or service marks of Align Technology, Inc. or one of its subsidiaries or affiliated companies and may be registered in the United States and/or other countries.*

*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, as amended (the “Exchange Act”). 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 fluctuations in currency exchange rates, inflation, higher interest rates, market volatility, threats or actual imposition of tariffs, threats of or actual economic slowdowns or recessions, our expectations and beliefs regarding customer and consumer purchasing behavior and changes in consumer spending habits, our expectations regarding product mix, product launches, product pilots 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 and potential collaboration opportunities, 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 expectations regarding our tax positions and the judgements we make related to our tax obligations, 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 impacts or 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 and ability to repatriate foreign earnings, 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 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**

### **Item 1. Business.**

#### ***Our Company***

Align Technology, Inc. (“we,” “us,” “our,” “Align” or the “Company”) is a global medical device company primarily engaged in the design, manufacture and marketing of Invisalign<sup>®</sup> clear aligners for the treatment of malocclusions, or the misalignment of teeth, by orthodontists and general dental practitioners (“GPs”), Vivera<sup>™</sup> retainers for retention, iTero<sup>™</sup> intraoral scanners and services for dentistry, and exocad<sup>™</sup> 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 the Align<sup>™</sup> 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<sup>™</sup> 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 iTero 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 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](http://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, 2024, Clear Aligner net revenues represented approximately 81% of worldwide net revenues, while Systems and Services net revenues represented the remaining 19%. We sell the majority of our products and services 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 furthermore 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), ultrasonic and UV electronic cleaning devices, 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, over 19 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 scanners are used by dental professionals, 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

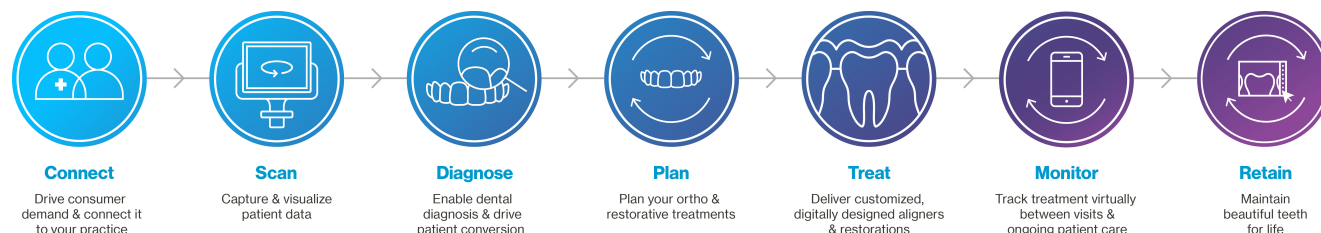
### *Align™ Digital Platform*



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 exceptional, modern treatment experiences and outcomes to patients 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 digital treatment experience and generate interconnected workflows and treatment solutions, that includes the following key components:



- **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, 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 intraoral scanners and exocad CAD/CAM 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™ intraoral scanners, including those with 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. Some of the tools that support this stage are ClinCheck® Pro 6.0, ClinCheck® Plan Editor, ClinCheck® In-Face Visualization, ClinCheck® Live Update, Invisalign® Practice App, Invisalign® Personalized Plan, CBCT Integration for ClinCheck® software, Clincheck® Smile Video, Invisalign Smile Architect™, iTero™ Design Suite, exocad Dental CAD™ software and exocad Dental CAD™ 3.2 Elefsina 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. The Invisalign® Palatal Expander System and the Invisalign® System with mandibular advancement featuring enhanced precision wings are additional products that support patient treatment.
- **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 AI, 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 2024, we launched several new products and technologies that further enhance the Align™ Digital Platform, including the iTero Lumina™ intraoral scanner, iTero Multi-Direct Capture™ technology, Clincheck® Smile Video, iTero™ Design Suite, Invisalign Smile Architect™ with treatment planning software with Multiple Treatment Plans, Invisalign® Outcome Simulator with Multiple Treatment Simulation and Align™ Oral Health Suite with new comparison tools.

### ***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 traditional metal wires and brackets, 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. Our business strategy remains focused on increasing our share of the existing market of orthodontic case starts compared to brackets and wires, 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 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, we have developed solutions to enable doctors to diagnosis and drive patient conversion from considering treatment to starting treatment – providing tools to support diagnosis of 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, approximately 94% of prescription orders for our Invisalign System are now submitted via digital scan, increasing the accuracy of treatment plans, reducing the time from when a doctor submits a prescription to the time a patient receives the clear aligners, and helping to decrease the carbon footprint resulting from elimination of the initial or upfront shipment of a patient's PVS impressions to the doctors and shipping those PVS impressions back to us.

*Computer-simulated treatment plan.* Our ClinCheck® Pro cloud-based treatment planning software is the cornerstone of the Align™ Digital Platform. ClinCheck Pro leverages proprietary algorithms based on the insights from data from over 19 million patients treated worldwide. Using the digital scans or PVS impressions, any specific doctor preferences and digital data provided, we generate a proposed custom, three-dimensional ClinCheck® treatment plan using proprietary software developed through significant, ongoing research and development investments spanning over 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 can be affixed to a patient's teeth to increase the biomechanical force on a specific tooth or teeth in order to affect the desired movement(s).

*Treatment plan review and approval by an Invisalign-trained doctor.* The patient's proposed ClinCheck treatment plan is then made available to the prescribing dental professional via our Invisalign Doctor Site, enabling the dental professional to evaluate projected tooth movement as it progresses from initial to final position and compare treatment plan options to best meet the dental professional's treatment objectives. By reviewing, modifying as needed and approving an acceptable 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 for 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 a patient's ClinCheck treatment plan.

*Shipment to the dental professional and patient clear aligner wear.* Once manufactured, each clear aligner for a patient's doctor-approved treatment plan is typically shipped directly to the dental professional. The majority of doctors then distribute each clear aligner to their patients. Each set of clear aligners (one clear aligner for the lower and a second for the upper jaw) 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 as and 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 their 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 doctor-approved treatment plan 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 products in our Invisalign System offered in various regions as they typically correspond to the severity of malocclusion and length of anticipated treatment.

Malocclusion	Very Mild	←	Moderate	→	Severe
Product	Invisalign® Express Package	Invisalign® Lite Package	Invisalign Go™ (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	Up to 2mm AP correction, crowding/spacing, lower incisor extraction, pre-restorative	No AP correction, mild to moderate crowding, spacing, lower incisor extraction, pre-restorative tooth movement from 2nd premolar to 2nd premolar (5x5)	Class I, mild AP correction, 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 progress or needs deviate 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, 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 sets of additional clear aligners included prior to the treatment expiration date, rather than the five-year treatment expiration date with unlimited additional clear aligner sets prior to the treatment end date offered under the Invisalign Comprehensive Package.

### 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. DSP is currently available in North America, Latin America, and certain countries in Europe.

*Invisalign Go Packages.* In various markets we also offer Invisalign Go™, Invisalign Go™ Express and Invisalign Go Plus, which are streamlined non-comprehensive packages designed for GPs to more easily identify and treat patients with mild-to-moderate malocclusion cases, expand arch width, align anterior teeth prior to restorative treatment, and move teeth from second pre-molar to second pre-molar. These packages include case assessment support, simplified ClinCheck treatment plans and a progress assessment feature for case monitoring.

### Non-Case Products:

The Comprehensive and Non-Comprehensive clear aligner packages described above are distributed in cases, meaning that all the sets of clear aligners required for all the stages of a doctor-approved treatment plan are delivered in a case. We also sell 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 United States.

*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 Invisalign® clear aligners or Vivera retainers.

### New Products/Feature Enhancement

*Invisalign® Palatal Expander System.* In December 2023, we received 510(k) clearance in the United States for the Invisalign Palatal Expanders. Invisalign Palatal Expanders are intended for use in rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw) with primary, mixed, or permanent dentition. The Invisalign Palatal Expander System consists of a series of removable devices staged in small increments of movement to expand a patient’s narrow maxilla to a position determined by their treating doctor. Each direct 3D printed device is customized to the patient’s unique anatomy based on an iTero™ intraoral digital scan. A palatal expansion treatment plan and device design are then developed using our proprietary orthodontic software. The Invisalign Palatal Expander is our first direct 3D printed orthodontic device. Combined with Invisalign First™ Phase 1 clear aligners, Invisalign Palatal Expanders provide doctors with a full early intervention treatment solution such as Phase 1, an early interceptive orthodontic treatment for young patients. The Invisalign Palatal Expander System is currently available in the United States, Canada, Australia, New Zealand, Hong Kong, Singapore, Japan and certain countries in EMEA. The Invisalign Palatal Expander System is expected to be commercially available in additional markets, pending regulatory approvals.

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. We believe 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. Direct fabrication offers the transformative potential of design flexibility that goes beyond what the current thermoforming technology allows. This will potentially allow us to design unique appliances

that may perform even better than our existing ones and address unmet market needs. We expect to pilot our first devices on this platform with 3D printed retainers in the first half of 2025.

### *Smart Technology: SmartTrack™, SmartForce™ and SmartStage™*

Smart technology is applied in the development of Invisalign treatments and leads to more precise control of individual and multiple tooth movements. We use a force driven system in our Invisalign clear aligners such that the next clear aligner is shaped so that when inserted, the clear aligner stretches and applies the desired force 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 Material.* SmartTrack clear aligner material is a patented, custom-engineered Invisalign clear aligner material that provides gentle, more constant force to improve control of 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 a longer period of 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 Attachments.* SmartForce attachments are small tooth-colored shapes that attach 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 helps patients decide to undergo treatment and improve treatment outcomes and satisfaction. The accuracy of digitally scanned models substantially reduces the rate of restoration "remakes," which results in patients being recalled to dental offices less often and experiencing shorter treatment times for the restoration work because fewer procedures are required after teeth are aligned and spaced optimally, 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™ intraoral scanner 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 above the gingiva in real time, without using harmful radiation. 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. We received 510(k) clearance in the United States 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 (“AI”)-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 remove the need for intraoral photos. 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 with minimal maneuvering. 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. We expect to launch the restorative software on the iTero Lumina intraoral scanner by the end of the first quarter of 2025.

*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 the 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 Health Suite.* The Align™ Oral Health Suite is a digital interface designed to enhance dental consultations and drive patient acceptance of dental treatment. It offers a modern approach to dental examinations, featuring an innovative clinical framework 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 intraoral 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 27 years, Align has helped doctors treat over 19 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 increasing awareness of our products and by making them available in more countries to more customers and consumers. We continue expansion of our sales and marketing by reaching into new countries and regions, including new areas in Africa and Latin America. As of the end of 2024, 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 2024, we have 13 fabrication and treatment planning 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 form the foundation of our manufacturing strategy, which continues 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 2025 by investing in resources, infrastructure and initiatives that help drive Invisalign treatment growth, position our iTero 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 strive to enable GPs, who have the potential to treat the general patient 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 intraoral 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. DSOs represent a large and growing opportunity to help drive adoption of digital technology across the dental industry. We have well established relationships with many DSOs globally that recognize the benefits of digital workflows enabled by our portfolio of products and services that make up the Align™ Digital Platform, including increased practice efficiency and profitability, as well as delivering a better patient experience from shorter cycle times and customer proximity. We have and may continue to financially invest in or explore collaborations with key ecosystem partners, including DSOs, whose missions and visions align with our own vision, strategy, business model and goals.
- *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, we continue to offer additional dental-related Invisalign Accessory Products under the Invisalign brand name available in certain e-commerce channels in the United States. The initial stage of the Align™ Digital 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, and Invisalign® Virtual Appointment. The Align™ Digital Platform also 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, that integrates iTero diagnostic aid and visualization tools, such as iTero NIRI, iTero Occlusogram, iTero TimeLapse and Invisalign Outcome Simulator Pro with multiple treatment plans.

- *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, 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 believe this allows us 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 also perform final scanner assembly in Blonie, Poland and Juarez, Mexico; as well as 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 of 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 compliance to this standard and other international regulations. We maintain 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 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 include complex software algorithms and solutions, including AI 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. In addition, we have invested in developing technologies that will allow us to directly print the devices that may help us improve and streamline the processes as well as the performance of devices. 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 and shipping issues, production manufacturing software system issues, quality and safety 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, having manufacturing facilities in key regions 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 and climate-related risks such as 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 or sole source 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 trained doctors to provide treatment.

We provide training, marketing and clinical support to orthodontists and GPs. As of December 31, 2024, we had approximately 130,370 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 iTero 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 15th year in 2024 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, 2024, we had 1,000 active U.S. patents, 1,063 active foreign patents, and 1,012 pending global patent applications. Our active U.S. patents expire between 2025 and 2043. When patents expire, we lose the protection and competitive advantages they provide, 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 Part I, 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 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. However, many of these typical seasonal patterns have been impacted by changes in foreign exchange rates, military conflicts, inflation and other macroeconomic challenges. It remains unclear when or if these seasonal fluctuations will return to historical norms. Consequently, seasonal trends have and may continue to cause fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

### ***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 United States. 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 United States.

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 Part I, 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 Regulations***

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 AI standards in any country in which we currently market our products, could cause commercial disruption and/or subject us to sanctions and fines. Delays in receipt of, or a failure to receive, such marketing authorizations, or the loss of any previously received authorizations, could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Our customers are healthcare providers that may be reimbursed by state or federal funded programs such as Medicaid, a foreign national healthcare program, or private pay insurance, each of which may offer some degree of oversight. As a medical device manufacturer and seller, we are subject to transparency reporting laws (also known as sunshine laws) that in certain countries and U.S. states require us to report transfers of value to healthcare professionals that perform services or receive other items from us (e.g., meals, travel, branded promotional or educational items, or other benefits of value). Enforcement actions and associated efforts to respond or defend against enforcement actions can be expensive, and any resulting findings carry the risk of significant civil and criminal penalties.

In addition, we must comply with numerous laws and regulations addressing privacy, data protection, data governance and cyber security. Many of these laws and regulations do or will soon regulate or restrict cross-border data transfers, such as in the United States, the EU, Switzerland, Brazil, China, Vietnam, Japan, Korea, Australia, New Zealand, the Kingdom of Saudi Arabia, Hong Kong and other countries. Further, in the United States, we may be required to comply with laws and regulations addressing the collection, use, security and processing of protected health information and other information relating to individuals, including the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its implementing rules. The HIPAA Standards for Privacy of Individually Identifiable Health Information (“Privacy Standards”) and the Security Standards for the Protection of Electronic Protected Health Information under HIPAA and the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH Act”) (the “Security Standards”) are the subjects of final and proposed rule amendments, respectively, reflecting the rapidly evolving nature of these laws and regulations. Additionally, many U.S. states maintain laws and regulations addressing privacy, data protection, data governance and cybersecurity. Like many other companies, we must work to ensure our global privacy program framework incorporates applicable requirements of new and modified laws and regulations in relevant jurisdictions to support our efforts to ensure that our product innovations and our associated practices comply with these increasingly complex laws and regulations.

Legislatures and regulators globally are proposing, and in certain cases have enacted, new laws or regulations regarding privacy, data protection, data governance and cybersecurity that could require us to modify our policies and practices in order to comply with new and evolving obligations relating to these matters. Information regarding risks associated with data security and privacy may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading “*Risk Factors*.”

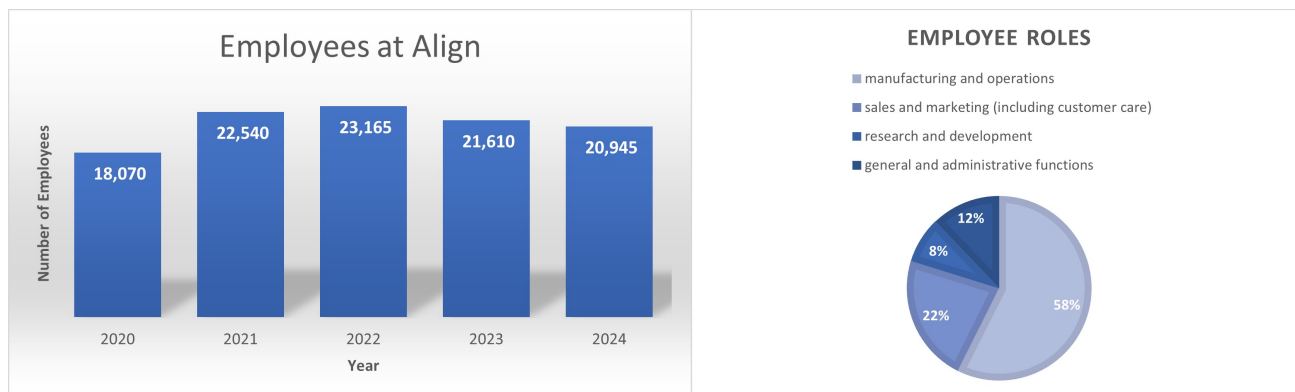
### ***Environmental Laws and Regulations***

We are subject to numerous international, federal, state and local environmental laws, including provisions that regulate the purchase, use, distribution, and environmental impact of hazardous substances used in our operations, contained within our products and the packaging associated with our products. We are also subject to environmental laws applicable to our manufacturing facilities and operations, including environmental health, safety and sustainability regulations. The number and rate at which these regulations are being proposed and implemented are increasing at the regional, country and local territorial levels, requiring greater diligence, governance and skills to manage. We may be required to incur significant costs to comply with existing and new laws and regulations in the future. Information regarding risks associated with environmental laws and regulations may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading “*Risk Factors*.”

### ***Human Capital***

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

As of December 31, 2024, we had approximately 20,945 employees, a decrease of approximately 3.1% and 9.6% over December 31, 2023, and December 31, 2022, respectively. The number of employees for each of the last five years and our employees’ roles as of December 31, 2024 are as follows:



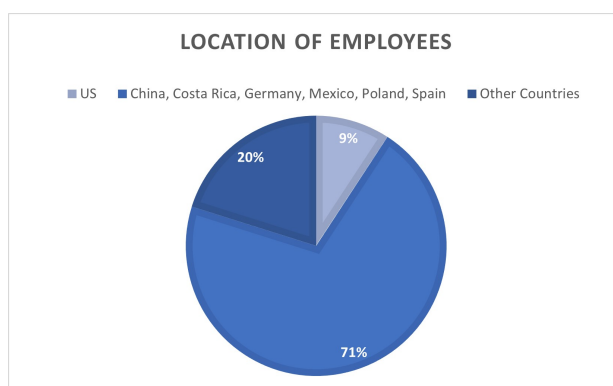
We are fundamentally a global organization with approximately 91% of our employees located internationally, primarily in direct-labor roles in our manufacturing and clinical treatment planning facilities. Set forth in the following paragraphs are some of the most important elements of our culture and commitment to our employees.

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

As part of our Board’s commitment to our employees and communities, our Board has delegated oversight responsibility of our policies and practices that foster Align’s sustainability and cultural initiatives, policies, practices, and programs to our

Nominating and Governance Committee. Additionally, our Compensation and Human Capital Committee has oversight responsibilities of all human capital management strategies, programs and policies. Our Compensation and Human Capital Committee regularly reviews and discusses key performance indicators regarding human capital management that allow it to monitor trends on issues such as total headcount, employee hiring, recruiting, attrition, career development, compensation, benefits, workplace culture, and other measures of employee engagement and interest to management and the committee.

We believe our success continues to be driven by our focus on integrating and welcoming employees across the globe and of all different backgrounds, orientations, beliefs, perspectives and capabilities into our workforce. Our employees bring a positive mix of ethnic and culturally diverse backgrounds to the 47 different countries in which we operate. Our largest population of employees work in Mexico followed by Costa Rica and China. Employees in the United States represent approximately 9% of our global population.



Our management team is comprised of individuals from varying countries and nationalities who are committed to promoting and encouraging the health and well-being of our employees at work, at home and in society in general.

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

Our employees have also established and manage employee groups including employee resource groups which are based on shared characteristics or life experiences. These are open to all employees, including those who do not directly identify with other members.

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

Our efforts have resulted in numerous awards for our positive work environment and culture. Some of the certifications, awards and recognitions recognized or received in 2024 and 2025 include:

- Best Places to Work for Women in Korea
- Dun & Bradstreet Top Tech Companies to Work for in Israel
- Great Places to Work and Best Places to Work based on our employee-validated great workplaces in the following countries, Australia, Brazil, Canada, China, India, Italy, Korea, Singapore, Taiwan, Thailand, the United Kingdom, Vietnam and Raleigh, North Carolina (United States)
- Forbes America's Dream Employers, America's Best Midsize Employers, America's Best Employers for Engineers, America's Best Employers for New Grads
- Fortune, America's Most Innovative Companies
- LinkedIn Top Companies, Brazil
- Mercer China, Healthiest Workplace Award for Outstanding Women Care
- Newsweek, America's Greatest Workplaces; Greatest Workplaces for Mental Wellbeing America

- U.S. News & World Report - Best Companies to Work For and Best Companies to Work For in the Health Care Industry

We believe it is imperative to provide a vibrant employee experience and we value our employees' collective voices. Accordingly, we conduct employee surveys that utilizes a continuous employee listening strategy to collect employee feedback critical to improving our culture. This listening strategy includes globally managed pulse surveys, employee lifecycle surveys, and a self-service feature to support listening efforts. We use what we learn from the surveys to improve the employee experience, including enhancements to our workplaces, focus on employee connections, increased career development opportunities, support for relocated employees, and growth in our recognition programs and experiences. Our global response rates are consistently high, reflecting strong engagement by our employees.

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

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

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

At Align, we believe employees learn best when skill development is driven by the changing and immediate needs of our employees and by empowering all employees to take action and ownership of their careers. We also believe learning should be relevant and actionable as well as rooted in our purpose and values. Develop@Align enables our global employee population to access a diverse portfolio of approximately 1,800 self-directed courses in up to 80 languages. We also offer a full suite of custom leadership development programs, beginning with aspiring leaders, continuing with managers and directors, and culminating with executive development opportunities.

We also recognize we must continually evolve by providing employees with the resources they need to continue to learn, grow, and thrive. To this end, we created Voyage. Voyage is a global initiative that offers a set of tools, resources and a new mindset, empowering employees to start thinking differently about career growth by embracing development opportunities in new and sometimes unexpected ways. Our Voyage Compass helps employees experience their career through four distinct lenses: Self, Networks, Experience and Skills. Since its launch in 2022, over 45% of the population has interacted with Voyage, and there have been over 140,000 visits to the Voyage website. In addition to our navigation site, we annually host two Voyage Set Sail weeks, where we offer experiential learning for individuals and teams utilizing activities that keep professional development front and center in employees' minds.

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

We are furthermore committed to pay equity practices. We exceed minimum pay requirements for our manufacturing employees and regularly review our pay equity practices globally and locally to address discrepancies.

*Health, Wellness and Safety.* Our employees' health and well-being is critical to our success and their continuing achievements. We therefore offer a wide variety of robust programs and initiatives designed to promote the overall health and welfare of all our employees and their families. Every year, we sponsor the Month of Wellness, a month dedicated to well-being and a worldwide movement fostering employee health across our organization. Throughout the Month of Wellness, employees participate in a variety of activities such as informational sessions and health fairs and receive useful resources aligned to our wellness pillars - mental resilience, physical well-being and healthy living, social/family connections, and financial wellness. This provides employees with a variety of meaningful ways to embrace wellness and well-being through mindfulness, meditation, nutrition and mental wellness activities, exercise, hikes, yoga, volunteer activities, financial education sessions, social events and stress management.

Additionally, a primary objective is to prevent injuries and occupational diseases by focusing first and foremost on creating and maintaining safe environments. We have environmental, health, safety and sustainability personnel who are

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

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

- Since 2013 we have been a proud supporter of Operation Smile, a global medical nonprofit that has provided hundreds of thousands of free surgeries for people born with cleft lips and cleft palates in low and middle-income countries. For the fourth year, we sponsored Operation Smile’s International Student Leadership Conference, a powerful opportunity for youth in high schools and colleges around the world to develop leadership skills and impact their communities. As part of our 2024 sponsorship, we provided full scholarships for 74 participants and students personally impacted with a cleft condition. In addition, we covered a portion of the conference fee for all students to make this opportunity more accessible for all attendees. As of December 31, 2024, we had donated approximately \$3.0 million to Operation Smile.
- As part of Align’s commitment to improving oral health, we partnered with the INCAE Business School as they relaunched the CAHI Jeffe Fellowship in Health and Innovation to improve health services in Latin America. The CAHI Jeffe Fellowship brought together 23 leaders from six Latin American countries and focused on enhancing the quality, accessibility, and affordability of health services through a variety of programs. Align provided scholarships to two leaders from the program who focused on oral health education and expansion of dental health for low-income populations.
- For 17 years we have supported America’s ToothFairy, an organization with a mission to ensure underserved children in the United States have access to dental care and learn about oral health by supporting nonprofit clinics and community partners. As of December 31, 2024, we have provided almost \$2 million for the foundation’s operational expenses and children’s oral health programs. As Title Sponsor of the HERO Program since 2019, we have helped the program reach an estimated 2.7 million children, caregivers, and parents. During America’s ToothFairy’s 2024 fiscal year, which ended June 30th, the HERO Program positively impacted more than 900,000 children and caregivers, including:
  - More than 600,000 children—33,500 of whom speak a language other than English—who were reached with downloadable resources accessed from AmericasToothFairy.org,
  - 43,250 children taught with ToothFairy 101<sup>®</sup> Community Education Kits distributed to educators, public health workers, and oral health professionals, and
  - Nearly 268,000 people who were reached through two sponsored awareness campaigns that included educational materials and social media kits.

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





### ***Available Information***

Our corporate website address is [www.aligntech.com](http://www.aligntech.com), and our investor relations website address is <http://investor.aligntech.com>. The information on or accessible through either of these websites is not incorporated by reference into this Annual Report on Form 10-K, and the above references to these website URLs are intended to be inactive textual references only. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our proxy statement on Schedule 14A for our annual stockholders’ meeting and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act are available, free of charge, on our investor relations website as soon as reasonably practicable after we electronically file or furnish such material with the Securities and Exchange Commission (“SEC”). Further, the SEC maintains an internet site (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding our filings with the SEC.



## Information about our Executive Officers

The following table sets forth certain information regarding our executive officers as of February 28, 2025:

Name	Age	Position	Period
 Joseph M. Hogan	67	<i>President and Chief Executive Officer of Align</i> <ul style="list-style-type: none"> <li>• Chief Executive Officer of ABB</li> <li>• Chief Executive Officer of GE Healthcare</li> </ul>	2015-Present 2008-2013 2000-2008
 John F. Morici	58	<i>Chief Financial Officer and Executive Vice President, Global Finance of Align</i> <ul style="list-style-type: none"> <li>• Chief Financial Officer and Senior Vice President, Global Finance of Align</li> <li>• Chief Financial Officer of Align</li> <li>• EVP and Managing Director of NBC Universal North America Home Entertainment</li> <li>• CFO/Chief Operating Officer of NBC Universal North America Home Entertainment</li> <li>• Senior Vice President and Chief Financial Officer of NBC Universal North America Home Entertainment</li> </ul>	2022-Present 2018-2022 2016-2018 2014-2016 2011-2014 2007-2011
 Julie Coletti	57	<i>Executive Vice President, Chief Legal and Regulatory Officer of Align</i> <ul style="list-style-type: none"> <li>• Senior Vice President, Chief Legal and Regulatory Officer of Align</li> <li>• Vice President, Associate General Counsel, Strategic Commercial Affairs of Align</li> <li>• Vice President, Global General Counsel and Chief Compliance Officer of Danaher</li> <li>• Vice President, Chief Legal Officer and Corporate Secretary of Bayer HealthCare's MEDRAD/Radiology and Interventional Division</li> </ul>	2022-Present 2019-2022 2018-2019 2013-2017 2007-2013
 Stuart Hockridge	53	<i>Executive Vice President, Global Human Resources of Align</i> <ul style="list-style-type: none"> <li>• Senior Vice Present, Global Human Resources of Align</li> <li>• Vice President, Global Human Resources of Align</li> <li>• Vice President of Talent of Visa</li> </ul>	2022-Present 2018-2022 2016-2018 2013-2016

### Item 1A. Risk Factors.

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

#### Macroeconomic and External Risks

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

Macroeconomic conditions impact consumer confidence and discretionary spending, which can adversely affect demand for our products. Consumer spending habits are affected by, among other things, inflation, fluctuations in foreign currency exchange rates, consumer confidence, general economic weakness, actual or potential slowdowns or recessions, pandemics, wars and military actions, employment levels, wages, debt obligations, discretionary income, interest rates, volatility in capital and perceptions of current and future economic conditions. Macroeconomic conditions can, among other things, reduce or shift spending away from elective procedures, drive patients to pursue less costly orthodontic treatments, decrease the number of orthodontic case starts, reduce patient traffic in dentists' offices, or reduce demand for dental services generally. Further, decreased demand for dental services can cause dentists and labs to postpone investments in capital equipment, such as intraoral scanners and CAD/CAM equipment and software. The declines in, or uncertain economic outlooks for, the United States, Chinese, European and certain other international economies have and could in the future materially adversely affect consumer and dental practice spending. Increases in the cost of fuel and energy, food and other essential items as well as higher interest

rates have and could in the future reduce consumers' disposable income, which could cause a decrease in discretionary spending for our products.

Inflation has and may continue to adversely impact spending and trade activities, and may unpredictably impact global and regional economies. Efforts by central banks and federal, state and local governments to combat inflation could result in an economic recession or slowdown or adversely impact consumer spending for a prolonged period of time. Higher inflation has and may continue to increase domestic and international shipping costs, raw material prices and labor rates, which could adversely impact the costs of producing, procuring and shipping our products. Our products or one or more of the materials or components of our products may also be subject to tariffs imposed by the United States or other countries. We may not be able to fully mitigate the impact of the increased costs or pass price increases on to our customers, resulting in downward pressure on our operating results. Attempts to offset cost increases with price increases may reduce sales, increase customer dissatisfaction or otherwise harm our reputation. Any of these events could materially affect our business, financial condition or results of operations.

We have significant international operations and sales and are therefore exposed to fluctuations in foreign currencies that have and may continue to adversely impact our business, financial condition or results of operations. Although the U.S. dollar is our reporting currency, a large portion of our net revenues and expenses are generated in foreign currencies. While we forecast our balance sheet exposures to foreign currency fluctuations and utilize foreign currency forward contracts to moderate the impact of exchange rate fluctuations on certain assets and liabilities, these contracts may not eliminate our exposure to fluctuations in foreign currency. Currency exchange rate fluctuations have and may continue to materially adversely affect our results of operations and cash flows.

***Our business, financial condition and results of operations could be impacted by geopolitical events, tariffs, trade and international disputes, wars, military actions and terrorism, or major public health crises.***

Geopolitical events, tariffs, trade and international disputes, wars, military actions and terrorism, or major public health crises have and could in the future harm or disrupt international commerce and the global economy, and could materially adversely affect our business with our customers and consumers, suppliers, contract manufacturers, distributors and other business partners. Such events have and could result in, among other things, supply chain and trade disruptions, changes in diplomatic and trade relationships, new tariffs and retaliatory tariffs, trade protection measures, trade sanctions, customs inquiries or restrictions, boycotts, reduced consumer spending, government shut downs, cyberattacks, energy shortages or power outages, energy rationing that adversely impacts our manufacturing facilities, rising fuel or rising costs of producing, procuring, and shipping our products, constraints, volatility or disruption in the financial markets, deaths or injuries to our employees, restrictions and shortages of food, water, shelter and medical supplies, data or information exchange, disruptions, interruptions or limitations in telecommunication services, critical systems or applications reliant on a stable and uninterrupted communications infrastructure, and protests that may impact delivery of our products to customers or destruction of property.

Tariffs or proposed tariffs, such as those on Chinese, Mexican, Canadian or other foreign goods, and any retaliatory trade measures in response may increase the cost of our products and the components and raw materials used to make them. Specifically, we manufacture clear aligners in our facility in Mexico and ship them to the United States, primarily for our United States customers with the remainder eventually shipping to other international locations. Tariffs would result in additional costs for our products, which may impact operating margin, reduce demand for our products and adversely impact our gross margin. Foreign countries may also adopt or rescind other measures, such as controls on the import or export of goods, technology or data, including personal data, that could adversely impact our operations and supply chains or limit our ability to offer certain products and services. These measures could require us to take various actions, including changing suppliers, where we manufacture our products, or restructuring business relationships. Complying with new or revised trade restrictions may be expensive, time-consuming, disruptive to our logistics and operations, and more costly for us and our customers. Such restrictions may be announced with little or no advance notice and we may be unable to effectively mitigate any adverse impacts in a timely manner or at all.

Military conflicts have and may in the future materially adversely impact the economies in which we operate. Our iTero operations, headquartered in Israel, are close to areas that have been affected by ongoing violence and military action, which may impact our employees and our iTero business and operations. Some employees and consultants in Israel have been called for military service in the current conflict and they may be absent for certain periods of time. Furthermore, our facilities may be damaged or our manufacturing capability or delivery schedules may be impacted as a result of the ongoing conflict. Our supply chains and demand for our products could be impaired as a result of hostilities, export and import restrictions, sanctions or boycotts. These events could disrupt ongoing operations and may materially impact the logistics, timing and cost of shipping of our products and materials or our ability to operate out of impacted areas. Additionally, 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 and each event could, individually or in the aggregate, materially adversely affect our business, financial condition, and results of operations.

***Our operations may be impacted by natural disasters, which may become more frequent or severe as a result of climate change, and may adversely impact our business, financial condition and results of operations, as well as those of our customers and consumers, suppliers, contract manufacturers, distributors and other business partners.***

Natural disasters such as earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, urban fires and extreme weather conditions can cause deaths, injuries and major public health crises, power outages, property damage, restrictions and shortages of food, water, shelter and medical supplies, telecommunications failures, materials scarcity, price volatility and other adverse consequences. If a natural disaster occurs in a region where one of our facilities or those of our customers or suppliers are located, our or their employees or facilities could be impacted, valuable research could be lost, and our ability to create treatment plans, respond to customer inquiries or manufacture and ship our products could be compromised, causing significant delays and reputational harm. Climate change could increase the frequency and severity of natural disasters and could change the supply, demand or availability of sources of energy or resources material to manufacturing our products and operations. It could also affect the availability or cost of materials, goods, and services on which we and our suppliers, contract manufacturers, distributors and other business partners rely, which could materially adversely impact our business, financial condition and results of operations.

## **Business and Industry Risks**

***Demand for our products and services may not increase or may decrease for many reasons, including resistance to the innovative and business-model-disruptive nature of some of our products and services, which could have a material impact on our business, financial condition and results of operations.***

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

***Our net revenues depend primarily on sales of the Invisalign System and iTero intraoral scanners and declines in sales or the average selling price (“ASP”) of these products may adversely affect net revenues, gross profit, and net income.***

Our net revenues are primarily dependent on sales of the Invisalign System and iTero intraoral scanners. Of the two, we expect the Invisalign System to continue to represent the majority of our net revenues, making sales of it critical to our success.

The ASPs of our products, particularly the Invisalign System, are influenced by numerous factors, including the mix of product treatment packages, geographical mix, channel mix and timing of products sold (particularly the timing and quantity of orders for additional clear aligners for certain Invisalign products) and foreign currency exchange rates. In addition, we sell our products at different prices and with varying shipping and handling charges or processing fees that may differ by country. Our ASPs for the Invisalign System and iTero intraoral scanners have been and could in the future be adversely affected if:

- we offer promotions or general or volume-based discount programs, product or services bundles, large account sales or consumer rebate programs;
- participation in promotions or programs unexpectedly increases, decreases or changes demand in material ways;
- our geographic, channel or product mix shifts to lower-priced products or to products with a higher percentage of deferred revenue;
- we decrease prices or are unable to increase prices on one or more products or services in response to increasing competitive pricing pressures;
- we introduce new or change existing products or services, or modify how we market or sell any of our new or existing products or services;
- we modify our pricing strategies for certain products or adjust pricing for certain items based on cancellation fees, shipping and handling charges or processing fees;
- we participate in government tenders, such as volume-based procurement in China; or
- our critical accounting estimates materially differ from actual results.

To stimulate product and services demand, we have a history of offering volume discounts, price reductions, and other promotions to targeted customers and consumers and releasing lower priced products. These promotional campaigns and lower-priced products have had, and may in the future have, unexpected and unintended consequences, including reduced net revenues, gross margins, operating margin and net income, ASPs and volume.

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

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

unattractive, particularly as competitors incorporate AI and machine learning into new or existing services and technologies that facilitate changes in doctor-patient interactions, expectations and treatment workflows. We may be unable to devote adequate financial resources to develop or acquire new AI technologies and systems in the future and sufficiently meet evolving industry trends and consumer demands.

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

Our iTero intraoral scanners are also facing increased competition from new and existing competitors. Our scanners compete with polyvinyl siloxane impressions and numerous new or existing intraoral scanners, as well as traditional bite wing 2D dental x-rays for detecting interproximal caries. We have and may continue to experience competition with our scanners by competitors who introduce products at lower prices or with functionality that better meets customer demand.

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

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

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

- successfully predict, timely innovate, develop, and launch new or improved technologies, applications, features, products and services to meet market demand and keep pace with changes in technology, customers' demands and industry standards;
- successfully and timely obtain regulatory approval or clearance of new or improved products or services from government agencies such as the FDA and analogous agencies in other countries;
- cost-effectively and efficiently develop, manufacture, quality test, market, dispose of and sell new or improved products and services, 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 offerings and technologies;
- differentiate our products and services from those of our competitors as well as other products and services in our own portfolio and successfully articulate the benefits to potential customers;
- design and manufacture products that achieve the clinical and practice outcomes we believe necessary for market acceptance;
- manage the impact of nationalism or initiatives encouraging consumer purchases from domestic vendors;
- qualify for third-party reimbursement for procedures involving our products or services;
- offer attractive and competitive products, services and subscription plans;
- encourage customers to adopt new or improved technologies and provide the needed technical, sales and marketing support to make new or improved product and services launches successful;
- manage government procurement program restrictions; and
- source and receive quality raw materials or parts from our suppliers.

If we fail to accurately predict the needs and preferences of customers and their patients, or fail to offer viable products or services, we may invest heavily in research and development that does not lead to significant revenues. Even if we successfully innovate and develop new or improved products and services, 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, financial condition and results of operations could be materially adversely impacted.

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

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

We are subject to various risks when making a strategic investment or acquisition and integrating the operations and cultures of acquired businesses within our own, which could materially impact our business, financial condition or results of operations, including that we may:

- fail to perform proper due diligence and inherit unexpected material issues or assets, including intellectual property (“IP”) or other litigation or ongoing investigations, accounting irregularities or compliance liabilities;
- fail to comply with regulations, governmental orders or decrees;
- experience information technology (“IT”) security and privacy compliance issues;
- invest in companies that generate net losses or are slow or fail to develop;
- not realize a positive return on our investment or determine that investments have declined in value, which could potentially require recording impairments;
- need to pay cash, incur debt or issue equity securities to pay for an acquisition, adversely affecting our liquidity, financial condition or the trading price of our common stock;
- find it difficult to implement and harmonize company-wide financial reporting, forecasting and budgeting, accounting, billing, IT and other systems due to inconsistencies in standards, internal controls, procedures and policies;
- require significant time and resources to effectuate the integration;
- fail to retain key personnel or harm our existing culture or the culture of an acquired entity;
- not realize material portions of the expected synergies and benefits of the investment or acquisition; or
- unsuccessfully evaluate or utilize the acquired technology or acquired company’s know-how or fail to successfully integrate the technologies acquired.

### **Operational Risks**

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

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

- changes in consumer and doctor demand;
- changes in manufacturing, packaging, delivery and inventory costs;
- the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due;
- our ability to collect payments;
- our acceptance of longer customer payment cycles;
- changes in the timing of revenue recognition and our ASPs;
- seasonal fluctuations;
- geographic, channel or product mix shifts to lower priced products or to products with a higher percentage of deferred revenue;
- improvements to or changes in our products, capabilities or technologies that replace or shorten the life cycles of legacy products or cause customers to defer or stop purchasing legacy products until new products become available;
- changes in costs and expenditures, including in connection with new treatment planning and fabrication facilities and the hiring and deployment of personnel;
- the timing of clear aligner treatment order submissions, acceptance, processing and fulfillment, which can cause fluctuations in our backlog; and
- timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows.

If we fail to accurately predict product demand, we may not have the appropriate level of our manufacturing capacity or that of one or more of our suppliers, staffing, materials, components, space, equipment or finished products. Specifically, our manufacturing process relies on sophisticated computer software and requires new technicians to undergo a long training process, often 120 days or longer. Additionally, production levels for our iTero intraoral scanners are generally based on forecasts and historic demand and we often place orders with suppliers for materials, components, sub-assemblies and finished products weeks or more in advance of projected orders. If we do not hire and train the appropriate number of technicians in anticipation of demand, our costs and expenditures may not align with our revenues or revenue growth. Additionally, to secure supplies for production of products, we periodically enter into non-cancelable minimum purchase commitments with vendors,

which could impact our ability to adjust inventory for declining demand. In addition, we may be required to purchase or lease additional or larger facilities and equipment to manage demand. If we fail to timely manufacture and deliver products to meet demand, this could damage our relationships with existing customers or harm our ability to attract new customers and adversely affect our business, financial condition and results of operations.

We may make business decisions that adversely affect our operating results such as modifications to our pricing policies and payment terms, promotions, development efforts, product releases, business structure or operations. The majority of our expenses, such as employee compensation and lease obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on 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 shortfalls. This variability and unpredictability could also result in our failing to meet the expectations of industry, financial analysts or investors.

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

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

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 one of these facilities is temporarily, partially or fully shut down, we may be unable to timely fulfill orders, which may negatively impact our reputation, business, financial condition and results of operations.

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

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

Additionally, we continuously upgrade and issue new software releases upon which customer facing manufacturing and treatment planning operations depend. Software applications and products containing software may contain errors or defects, especially when first introduced or released. The discovery of a defect, error, or security vulnerability in our products, software applications or IT systems, incompatibility with customers' computer operating systems and hardware configurations with a new release or upgraded version or the failure of our products or primary IT systems, which we are unable to cure in a timely fashion, may cause adverse consequences. These may include delays or loss of revenues, significant remediation costs, market acceptance delays, data damage, loss, or unavailability, unintended disclosure or other processing of financial, health or other information relating to individuals, product recalls, loss of market share or increased service costs, any of which could have a material effect on our reputation, business, financial condition or results of our operations and the operations of our customers or our business partners.

***Products in our Systems and Services segment, such as our iTero intraoral scanners, are subject to software and hardware risks that, if improperly managed, could have a material adverse impact on our business and financial results.***

The success of our Systems and Services segment depends on the quality and reliability of our products. We face software and hardware risks related to the manufacturing, design, quality and safety of our complex, global installed base of iTero intraoral scanners, which are continually updated to add, expand, or improve features with new hardware we manufacture or components that we source, to integrate new or existing software or other components manufactured by third parties, or to provide repair or replacement parts, any of which may contain errors or exhibit failures, especially when products are first introduced. We may be unable to ensure that third party components or changes to them will be completely compatible with our iTero intraoral scanners, which could result in failures of our iTero intraoral scanners to perform as anticipated. Additionally, the third-party software integrated into or interoperable with our iTero intraoral scanners will routinely reach end of life, and as a consequence, certain applications and models may be exposed to additional vulnerabilities, including security risks, errors, and malfunctions that may be irreparable or difficult to repair. We may not timely and adequately remediate or implement corrective measures for such failures, including due to reliance on third-party providers or suppliers. Consequently, any remediation may be time-consuming and difficult to achieve, which may materially impact our customers and business partners, damage our reputation, and result in lost business and revenue opportunities, and could be materially costly. If our products experience component aging, errors, or performance problems, or do not otherwise satisfy our stringent quality processes and controls we may choose to or be compelled to recall certain products, which may include, product withdrawals from the market, labeling changes, design changes, customer notifications, and notifications to global regulatory bodies.

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

***We are highly dependent on third-party suppliers, some of whom are sole source suppliers, for certain key machines, components and materials, and our business, financial condition and results of operations could be materially adversely affected if supply is restricted or ends or the price materially increases.***

We are highly dependent on our supply chain, particularly manufacturers of specialized and customized scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our iTero intraoral scanners. We maintain single and sole supply relationships for many of these machines and materials. By using single and sole suppliers in limited locations for materials and manufacturing, we are exposed to multiple supply chain vulnerabilities. We are reliant upon manufacturers that we contract with for quality and stability and any failures on their part may have an impact on our ability to supply our products.

Because of our dependence on our suppliers, changes in key relationships can materially disrupt our supply chain. For instance, we may be unable to quickly establish or qualify replacement suppliers, which could create production interruptions, delays and inefficiencies. Finding substitute manufacturers may be expensive, time-consuming or impossible and could result in significant interruptions in the supply of one or more products, product retesting or additional product registration, causing us to lose revenues and damage customer relationships. Technology changes by our service providers, vendors and other third parties could disrupt access to required manufacturing capacity or require expensive, time-consuming development efforts to adapt and integrate new equipment or processes. In the event of technology changes, delivery delays, labor stoppages or shortages, or 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 these distributors do not comply with applicable laws or our internal procedures.***

In addition to our direct sales force, we have and expect to continue to use distributors to import, market, sell, service and support our products and services. Our distribution agreements are generally non-exclusive and terminable by either party with customary notice. If alternative distributors cannot be quickly found and trained in the use, marketing, sales and support of our products and services, our revenues and ability to sell or service our products and services in key markets could be adversely affected. These distributors may also choose to sell alternative or competing products or services. In addition, we may be held responsible for the actions of these distributors, their employees and agents for compliance with laws and regulations, including fair competition, bribery and corruption, import and export compliance, safety, data privacy, false advertising or unfair and deceptive trade practices, and marketing and sales activities. The conduct of these distributors may impact our reputation and brand and if they 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 depend on commercial freight carriers, primarily United Parcel Service, Inc., to deliver our products. If the operations of commercial freight carriers are disrupted or we fail to mitigate any disruptions, we may be unable to timely deliver products to our customers who may choose alternative products, causing our net revenues and gross margin to decline, possibly materially. Moreover, when fuel costs increase, our freight costs generally do 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 will be difficult to achieve our strategic priorities, which could materially adversely affect our business, financial condition and results of operations.***

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

We provide significant training to our personnel and our business will be harmed if our training fails to properly prepare them to perform the work required, we are unable to successfully instill technical expertise in new and existing personnel, or if our techniques prove unsuccessful or are not cost-effective. Moreover, for certain roles, this training and experience can make key personnel, such as our sales personnel, highly desirable to competitors and lead to increased attrition. It can take 12 months or more to train sales representatives to successfully market and sell our products and services and for them to establish strong customer relationships. The loss of the services and knowledge of our highly-skilled personnel may significantly delay or prevent the achievement of our development, operational or strategic objectives.

Additionally, seamless leadership transitions for key positions are critical to sustaining our culture and organizational success. If our succession planning is ineffective, it could adversely impact our business. We continually assess key personnel we believe are essential to our long-term success. Moreover, future organizational changes may cause 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 personnel, may be adversely affected.

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

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

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

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

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



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

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

### **Legal, Regulatory and Compliance Risks**

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

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

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

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

- the storage, transmission, disclosure, and other processing of, and security measures with respect to, personal, financial and medical information as well as healthcare records;
- processing and use of children's personal and health data;
- websites and application advertising, including that involving the use of cookies or involving the collection, use, disclosure, or other processing of data relating to individuals for marketing purposes;
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products and services; and
- the design, manufacture, marketing and advertising of our products and services.

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

Furthermore, before we can sell a new medical device or market a new use of, or claim for, an existing product, we frequently must obtain regulatory clearance or approval. For instance, in the United States, 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. Moreover, these laws may change, resulting in additional time, expense or loss of market access. If the requirements to market our products or services are delayed, we may be unable to offer them in markets we deem important. Additionally, failure to comply with applicable regulatory requirements could result in enforcement actions with sanctions, including fines, civil penalties and

criminal prosecution. Delays or failures to obtain or maintain regulatory approvals, clearances or to comply with regulatory requirements may materially adversely affect our domestic or international operations, and adversely impact our business.

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

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

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

In June 2024, the U.S. Supreme Court reversed its longstanding approach to evaluating administrative rulemaking under the *Chevron* doctrine, which provided for judicial deference to regulatory agencies, including the FDA. There may be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the courts. For example, this decision may result in more companies suing the FDA to challenge its longstanding decisions and policies, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit.

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

We retain confidential employee, applicant and customer personal, health and financial, and our own proprietary information and data essential to our operations. We rely on the effectiveness of our IT systems, policies and contracts and the policies of our third-party vendors, and their IT systems to safeguard information and data. Additionally, our cybersecurity controls depend on our customers, many of whom are individual or small healthcare providers with limited IT experience and inadequate or untested security protocols, to successfully manage data privacy and security requirements. It is critical that the facilities, infrastructure and IT systems on which we depend and the products and services we develop remain secure and be perceived as secure. Despite the implementation of security features in our products and services and security measures in our IT systems, we and our service providers, third-party vendors and other third parties could be targeted by or subject to physical break-ins, computer viruses and other malicious code, unauthorized or fraudulent access, programming errors or other technical malfunctions, hacking attacks, phishing and other social engineering attacks, malware, ransomware, employee error or malfeasance, cybersecurity attacks, malicious code, and other breaches of, or incidents impacting, IT systems or similar malicious or otherwise disruptive actions, including by organized groups and nation-state actors, which may disrupt or limit the availability of, or result in damage to, our IT systems and result in loss or unavailability of, damage to, or the unauthorized acquisition, use, disclosure, or other processing of confidential information. For example, we have experienced, and may again experience in the future, cybersecurity incidents, data incidents, and unauthorized internal employee exfiltration of information. This risk is exacerbated with the advancement of technologies like AI, which malicious third parties can use to create new, more sophisticated and more frequent or other attacks. There can be no assurance our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information or any other information we maintain or otherwise process.

Further, the frequency and sophistication of third-party cybersecurity attacks are increasing. Significant service disruptions, breaches, incidents, interruptions or other disruptive events impacting our infrastructure and IT systems, or other cybersecurity incidents, or any belief or reporting that any of the foregoing has occurred, could expose us to regulatory investigations, or other proceedings, private claims, demands, and litigation, impair our reputation and competitive position, distract 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 our products and services. Concerns over our practices with respect to privacy, data protection, data governance, and cybersecurity could adversely affect our reputation and deter customers and consumers from using our products and services. In addition, patient care could suffer, and we could be liable if our products, services or IT systems fail to timely deliver accurate and complete information. We have cybersecurity and other forms of insurance coverage related to cyberattacks, breaches, and other incidents

or security problems, but we cannot guarantee applicable insurance will be available to us in the future on economically reasonable terms or at all. Damages and claims arising from incidents may not be covered, may exceed coverage limits, and may not cover the time and effort we incur investigating and responding to any incidents, or other costs or liabilities, which may be material. The costs to eliminate, mitigate, or recover from security problems and cybersecurity attacks and incidents could be material and require us to implement additional or different security controls or other measures and, depending on the nature and extent of the problem and the products, services or IT systems impacted, such security problems and cybersecurity attacks and incidents may result in network, IT system interruptions or other disruptions, decreased product sales, data loss, damage, unavailability, or other liabilities, any of which may have a material impact on our operations, net revenues and operating results.

Additionally, our iTero intraoral scanners may be independently or collectively the target of cybersecurity incidents or attacks or subject to security vulnerabilities, bugs, errors, defects, or viruses or other malicious code. Due to the large and growing number of these decentralized devices, we may be unable, or not have the capacity, knowledge or infrastructure, to respond to or remedy a cybersecurity incident in a timely manner. Any such cybersecurity incident may cause loss or damage to us, our customers or strategic business partners or may cause further malfunctions in, or damage to, our products, services, or IT systems, damage to, or loss, unavailability, or unauthorized acquisition, use, or other processing of our data, or disruption, interruption or temporary cessation of our operations. Further, any such security breach or incident, or other cybersecurity incident, or any belief or reporting that any of the foregoing has occurred, may otherwise have a negative impact upon our business or reputation.

We are also subject to federal, state, and foreign laws and regulations respecting the security and privacy of patient healthcare information applicable to healthcare providers and their business associates, such as HIPAA, the HITECH Act, and the Privacy Standards and Security Standards, as well as those relating to privacy, data security, content regulation and consumer protection, such as the California Consumer Protection Act, as amended by the California Privacy Rights Act (as amended, the “CCPA”). The CCPA requires covered businesses that process personal information of California residents to disclose certain practices, provides California residents with data privacy rights, imposes operational requirements, and provides for significant civil penalties for violations as well as a private right of action for certain data breaches and statutory damages. There are limited exemptions under the CCPA for protected health information covered by HIPAA and certain other state laws, but the CCPA and other new and evolving state laws could impact our business activities. Numerous other states have enacted laws relating to privacy, data protection, data governance and cybersecurity that either are in operation or slated to go into operation over the next several years. Many of these laws are comprehensive privacy laws similar to the CCPA. States also are enacting laws addressing specific subject matter, such as Washington’s My Health, My Data Act, which includes a private right of action. Laws in all 50 U.S. states may require businesses to provide notice to individuals whose personal data has been disclosed as a result of a data breach. Outside of the U.S., relevant legal requirements continue to evolve. For example, the collection and use of health data and other personal information is governed in the EU by the General Data Protection Regulation (“GDPR”), which imposes significant obligations upon companies and rights for individuals, with substantial penalties for noncompliance up to the greater of €20,000,000 or 4% of the total worldwide annual turnover of the preceding financial year, and by certain EU member state-level legislation. Numerous other jurisdictions maintain similar legislation or other laws or regulations addressing privacy, data protection, data governance, or cybersecurity.

We are also subject to data export restrictions and international transfer laws and regulations that prohibit or impose conditions upon certain data transfers. The mechanisms upon which we and many other companies rely upon for European data transfers have been the subject of legal challenge, regulatory interpretation and judicial decisions by the EU courts and regulators, and may be subject to significant changes. Several countries, including the United States, China, Australia, and Japan, have established legal requirements for cross-border transfers of all or certain personal information and certain countries have also established legal requirements for data localization. These laws and regulations are constantly evolving and may be created, interpreted, applied or amended in ways that could restrict our activities in certain jurisdictions, limit our ability to provide our products and services in those jurisdictions, require us to modify our policies and practices and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data across borders. We have and likely will again in the future be required to implement new or expand existing data storage protocols, build new storage facilities, devote additional resources, and modify relevant policies or procedures to comply with the foregoing laws, any of which could be costly and which may adversely affect our business and our customers' businesses, our financial condition and our results of operations in those jurisdictions.

With laws, regulations and other obligations relating to privacy, data protection, data governance and cybersecurity imposing new and relatively burdensome obligations, and with substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. Further, any failure or perceived failure by us or our vendors, customers, or service providers to comply with our applicable policies or notices relating to privacy, data protection, data governance or cybersecurity, our contractual or other obligations to third parties, or any of our other legal obligations, laws, rules, regulations or standards relating to privacy, data protection, data governance or cybersecurity, may result in governmental investigations or enforcement actions, litigation, claims and other proceedings, harm our reputation, and could result in significant liability.

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

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

***Current and anticipated sustainability and social (“Sustainability”) laws and scrutiny of our Sustainability policies and practices may materially increase our costs, expose us to liability, and adversely impact our reputation, employee retention, willingness of customers and suppliers to do business with us and willingness of investors to invest in us.***

Our operations are subject to a variety of existing local, regional and global Sustainability laws and regulations, and we are and may be required to comply with new, broader, more complex and more costly Sustainability laws and regulations, such as the EU’s Corporate Sustainability Reporting Directive. Our compliance obligations span all aspects of our business and operations, including product design and development, materials sourcing and other procurement activities, product packaging, product safety, energy and natural resources usage, facilities design and utilization, recycling and collection, transportation, disposal activities and workers’ rights.

Sustainability regulations 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 from power generated using fossil fuels. The effects of greenhouse gas emission limits on power generation are subject to significant uncertainties, including the timing of new requirements, levels of emissions reductions and the scope and types of emissions regulated. Additionally, as Sustainability laws are increasing, customers and consumers may demand our products, packaging and operations be more sustainable, affect how we manufacture and package our products, increase our costs and those of our suppliers, and may result in manufacturing, transportation and supply chain disruptions if sustainable clean energy is not readily available in adequate amounts when required. Moreover, clean energy sources, coupled with reduced investments in traditional energy production and infrastructure, may not provide the predictable, reliable and consistent energy we, our suppliers and other business partners require.

Additionally, the sourcing and availability of metals used in the manufacture of, or contained in, our products may be affected by laws and regulations governing the use of minerals obtained from certain regions of the world like the Democratic Republic of Congo and adjoining countries. Our expanding geographic operations may increase the risk of purchasing “conflict minerals” and our diligence efforts to identify whether any of our products contain minerals impacted by these laws and regulations may not be accurate, adequate or complete. Other restrictions apply to the substances incorporated into our products, including the chemical compounds in our clear aligners, the electronics in our iTero intraoral scanners and the packaging in which they are shipped. These laws are proliferating and new substances subject to restrictions are added regularly and may require additional reporting or phasing out of certain chemicals and compounds such as per- and polyfluoroalkyl substances (PFAS). We may be required to re-design our products or identify new suppliers to maintain our compliance with these laws. Further, these laws and regulations may decrease the number of suppliers capable of supplying our needs, thereby negatively affecting our ability to manufacture products in sufficient quantities at competitive prices, leading customers to potentially choose competitive goods and services.

Meeting our obligations under existing Sustainability laws and regulations is costly for us and our suppliers, and we expect these regulations and costs to increase, in particular as the regulatory frameworks in each jurisdiction in which we operate become more complex and distinct. Additionally, regulators may perform investigations, inspections and periodically audit our compliance with these laws and regulations, and our efforts or operations may not be compliant. If we fail to comply with any requirements, we could be subject to significant penalties or liabilities and we may be required to implement new and materially more costly processes and procedures. Even if we successfully comply with these laws and regulations, our suppliers may not. We may also suffer financial and reputational harm if customers require, and we are unable to deliver, certification that our products are compliant. In all of these situations, customers may stop purchasing products from us, and may take legal action against us, which could harm our reputation, business, financial condition and results of operations.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders and customers have and could in the future focus on corporate Sustainability practices. Additionally, public interest and legislative pressure related to companies’ Sustainability practices has been evolving in recent years. If we fail to adopt Sustainability standards or practices as quickly as stakeholders desire, comply with or timely report on our Sustainability efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our brand, reputation, employee retention, business, financial performance, growth, and stock price may be adversely impacted.

***We have been incorporating and continue to work to further incorporate AI technologies into our products, services and IT systems. Implementation of AI and machine learning technologies may result in legal and regulatory risks, reputational harm or have other adverse consequences to our business.***

We have and are continuing to incorporate AI, including machine learning and independent algorithms, in certain of our products, services and IT systems, which is intended to enhance their operation and effectiveness internally and for our customers, consumers and suppliers. There can be no assurance that we or our customers will realize the expected benefits from these investments. AI innovation presents risks and challenges that could impact our business. Our, or our vendors', AI algorithms may be flawed. Our datasets or AI training algorithms may be insufficient or contain biased information.

Additionally, many countries and regions, including the EU, have proposed new and evolving regulations related to the use of AI and machine learning technologies. In Europe, the EU AI Act entered into force on August 1, 2024 which will become fully effective on August 2, 2026, with some provisions effective in February 2025. Other jurisdictions are considering similarly focused legislation. Although we do not engage in developing or providing AI systems for which their placement on the market, putting into service, or use would qualify as "prohibited AI practices," restrictions and obligations under this regulation, to the extent applicable to us, could have a negative impact on our business, financial condition and results of operations. Additionally, other jurisdictions have proposed, and in certain cases enacted, laws and regulations addressing aspects of the use and development of AI. The evolving AI regulatory environment may, among other impacts, result in:

- inconsistencies among AI regulations and frameworks across jurisdictions;
- onerous compliance, governance, research and development obligations that may require us to rework or reevaluate improvements to be compliant or result in the development of products that are unacceptable under new or revised regulatory frameworks;
- increased risk of regulatory enforcement and litigation related to our AI models;
- increased liability related to the use of AI by our customers, consumers or suppliers that are beyond our control;
- delays in the deployment of new products and services;
- competitive and reputational harm; and
- increased cybersecurity risks.

### **Intellectual Property Risks**

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

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

We rely on our portfolio of issued and pending patent applications in the United States 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. We may choose not to file a foreign patent application if the limited protections provided by a foreign patent do not outweigh the costs to obtain it. Further, third parties may file patents or develop IP strategies that prevent or limit the effectiveness of our patents.

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

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

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

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

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

### **Financial, Tax and Accounting Risks**

***If our goodwill, intangible or long-lived assets become impaired, we may be required to record material charges to income.***

Under U.S. GAAP, we review our goodwill annually and more frequently if we identify events or circumstances that indicate it is more likely than not 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 circumstances indicate the carrying value of the asset (asset group) may not be recoverable. The qualitative analysis performed by management to identify indicators of impairment or the quantitative analysis used to determine fair value requires management to exercise significant judgement in determining appropriate assumptions and estimates, including revenue growth rates, gross and operating margins, and discount rates. 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 material charges to earnings on our financial statements during the period in which any impairment of goodwill, intangible assets or long-lived assets is determined.

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

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

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

We are required to furnish in our Annual Report on Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting that includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including an assertion by management that our internal control over financial reporting were effective as of the end of our fiscal year. Our internal controls may become ineffective because of changes in personnel, updates and upgrades to or migration away from existing software, failure to maintain accurate books and records, changes in accounting standards or interpretations of existing standards, or changes to business models that may require adjustments to our financial reporting and, as a result, the degree of compliance of our internal control over financial reporting with the existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, and may require additional staffing and infrastructure investments and increases our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective, 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. This could cause our investors to lose confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

***Our effective tax rate may vary significantly from period to period, which could result in volatility of our operating results and adversely affect our financial results.***

We are subject to taxes in the United States and foreign countries. Various internal and external factors may impact our future effective tax rate. These include changes in the global economic environment, our legal entity structure or activities performed within our entities, our business operations, tax laws, regulations and/or rates, changes to existing accounting pronouncements, changes in interpretations of existing tax laws or regulations, the relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, overall levels of pretax earnings, settlements of income tax audits, non-deductible goodwill impairments, and changes in the valuation allowance offsetting deferred tax assets. Furthermore, we may continue to experience variation in our effective tax rate related to excess tax benefits or tax expense on stock-based compensation, particularly in the first quarter of each year when the majority of our equity awards vest.

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

Compliance with tax laws requires significant judgment concerning our worldwide provision for income taxes. Changes in tax laws or changes to how those laws are applied to our business could affect the amount of tax which we are subject to and the manner in which we operate. Specifically, the Organization for Economic Cooperation and Development (“OECD”) established the Inclusive Framework on Base Erosion and Profit Shifting (“BEPS”) to among other things, allocate greater taxing rights to countries where customers are located and establish a global minimum tax rate. Countries including EU member countries have enacted, are considering enacting, or have committed to enact the OECD/G20 Framework’s Pillar Two 15% global minimum tax, including Switzerland which is a significant jurisdiction for us. We continue to monitor the enactment of legislation to evaluate the impact of changing global tax laws, which could adversely affect our provision for income taxes or operations.

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. The positions we take regarding taxes as well as the amounts we collect or remit have and may continue to be challenged and we may be liable for failing to collect or remit all taxes deemed owed or the taxes could exceed our estimates. We have and may continue to dispute rulings or positions taken by tax authorities, which have and may continue to incur significant expenses, time, and effort to defend our positions.

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

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

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

- quarterly variations in our results of operations and liquidity, our ability to meet or exceed our forecasts and guidance or changes to or withdrawal of our previous forecasts and guidance;
- our ability to regain or sustain our historical growth rates;
- changes in recommendations or valuation models for our stock by the investment community, or speculation in the press or investment community regarding estimates of our net revenues, results of operations, or other key performance indicators;
- announcements by us, 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 macroeconomic, industry, or company-specific fundamentals, including the sentiment of retail investors (as it may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our common stock, fractional share trading, and other technical trading factors or strategies;
- stockholder activism or securities class action litigation;
- announcements regarding stock repurchases, sales or purchases of our common stock by us, our officers or directors, credit agreements, and debt issuances;
- announcements of technological innovations or new, additional or revised programs, business models, products, or product offerings by us, our customers, or competitors;
- key decisions in pending litigation, new litigation, settlements, judgments, or decrees;
- short selling or other hedging activity in our stock; and
- general economic market conditions, including rising interest rates, tariffs, inflationary pressures, recessions, consumer sentiment and demand, global geopolitical conflict, and industry factors unrelated to our actual performance.

In addition, the stock market in general, and the market for technology and medical device companies, in particular, often experience extreme price and volume fluctuations unrelated or disproportionate to corporate operating performance. Any such

fluctuations have and may continue to adversely affect the market price of our common stock. These broad market and industry factors may include market expectations of, or actual changes in, monetary policies that have the goal of easing or tightening interest rates such as the U.S. federal funds rate and austerity measures of governments intended to control budget deficits. Securities litigation, including securities class action lawsuits and securities derivative lawsuits, is often brought against an issuer following periods of volatility in the market price of its securities and we have not been exempt from such litigation.

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

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

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

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

#### **Item 1B. Unresolved Staff Comments.**

None.

#### **Item 1C. Cybersecurity.**

##### **Overview**

We have implemented a cross-functional information security program to assess, identify and manage material risks from cybersecurity risk, which includes seeking input from our employees, management, third-party vendors, the Audit Committee of the Board of Directors (“Audit Committee”) and the Board of Directors.

Our 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. In certain instances, incidents are escalated to certain members of our legal team who are responsible for, among other things, the accurate and timely disclosure of material cybersecurity incidents required under federal securities laws, including making the materiality determination and approving related securities disclosures.

##### **Risk Management and Strategy**

Our information security program devotes 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. Our information security program leverages the National Institute of Standards and Technology (NIST) and International Organization for Standardization (ISO) 27001 frameworks choosing to organize our cybersecurity risks into five categories: identify, protect, detect, respond and recover. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST and ISO frameworks as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our information security program is integrated into our overall enterprise risk management program. 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.

Our information security program also includes 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 users informed on current events.

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 its cybersecurity preparedness and our initiation or continued engagement with it. Additionally, third-party vendors are required to include security and privacy addenda to our contracts where determined 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.

As of the date of this Annual Report on Form 10-K, we have not identified any risks from known cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our 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.

For a discussion of our cybersecurity-related risks, see Part I, Item 1A of this Annual Report on Form 10-K under the heading “*Risk Factors*.”

## **Governance**

### *Role of Management*

To more effectively assess and manage 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 information security team, comprised of employees with an expertise in cybersecurity and information technology, regularly assesses the threat landscape and takes a holistic view of cybersecurity risks, with a layered cybersecurity strategy based on prevention, detection and response. Our information security team annually performs a cybersecurity enterprise risk assessment and presents the results to management and the Audit Committee. In addition, our internal audit team conducts periodic audits of the Company’s systems and cybersecurity processes, with findings reported to the Audit Committee and senior management.

### *Role of the Board of Directors and the Audit Committee*

Our Audit Committee has responsibility for overseeing and reviewing our cybersecurity, data privacy, and other information technology risks, controls and procedures, including our plans to mitigate cybersecurity risks and to respond to data breaches. Our Audit Committee also reviews with management any specific cybersecurity issues that could affect the adequacy of our internal controls and disclosure procedures and any public disclosures about our cybersecurity controls and procedures, the Board of Directors’ cybersecurity expertise, and its oversight of cybersecurity risk. The Audit Committee periodically reports on its review of cybersecurity risks and our cybersecurity program to our Board of Directors. In 2024, our CISO or his team met with the Audit Committee four times to discuss cybersecurity risks and threats.

**Item 2. Properties.**

We occupy several leased and owned facilities. As of December 31, 2024, 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 8 "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 Select Market under the symbol "ALGN." As of February 20, 2025, 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***

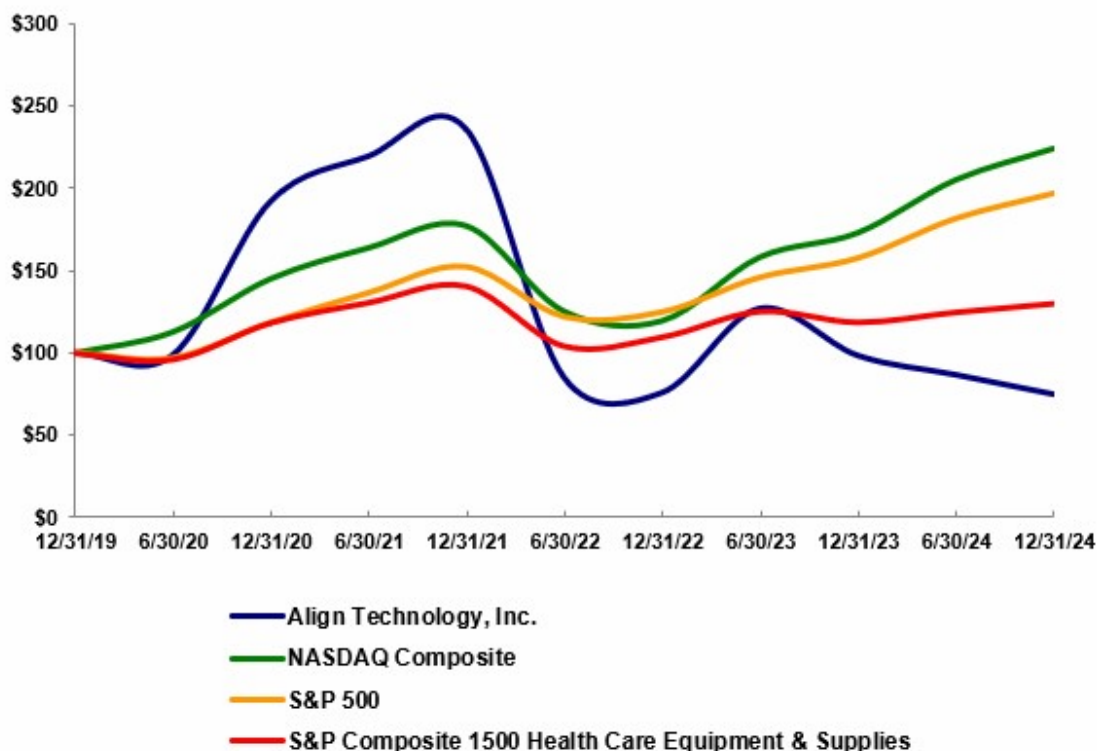
*Notwithstanding any statement to the contrary in any of our previous or future filings with the SEC, the following information relating to the price performance of our common stock shall not be deemed "filed" with the SEC or "soliciting material" under the Exchange Act or subject to Regulation 14A or 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 compares the 5-year cumulative total stockholder return on Align 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 Industry Index. The graph tracks the performance of a \$100 investment in Align common stock and each index (assuming reinvestment of all dividends) from December 31, 2019 to December 31, 2024. Past stock price performance is not necessarily indicative of future stock price performance.

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## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among Align Technology, Inc., the NASDAQ Composite Index, the S&P 500 Index and the S&P Composite 1500 Health Care Equipment & Supplies Index



\*\$100 invested on 12/31/19 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

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### Recent Sales of Unregistered 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, 2024:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
October 1, 2024 through October 31, 2024	83,029	\$ 217.18	83,029	\$ 482,000,000
November 1, 2024 through November 30, 2024	407,090	\$ 221.48	407,090	\$ 392,000,000
December 1, 2024 through December 31, 2024	419,848	\$ 225.49	419,848	\$ 297,100,000
Total	909,967		909,967	

<sup>1</sup> 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 ("January 2023 Repurchase Program"). See Note 11 "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 2024 compared to fiscal 2023 is presented under Results of Operations of this Form 10-K. Discussions regarding our financial condition and results of operations for fiscal 2023 compared to 2022 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, 2023, filed with the SEC on February 28, 2024, which is available without charge on the SEC's website at [www.sec.gov](http://www.sec.gov) and on our investor relations website at [investor.aligntech.com](http://investor.aligntech.com).

### Executive Overview of Results

#### *Trends and Uncertainties*

Our strategic priorities focus on four principal pillars for growth: (i) international expansion; (ii) general dental practitioners ("GP") 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 clear aligners, 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, we have fabrication facilities in three key regions 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, which has created a longer term, more stable environment for consistent hiring, retention and innovation in a variety of high technology locations.
- 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, products like Invisalign Go™ treatment, 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. DSOs represent a large and growing opportunity to help drive adoption of digital technology across the dental industry. We have well established relationships with many DSOs globally that recognize the benefits of digital workflows enabled by our portfolio of products and services that make up the Align™ Digital Platform, including increased practice efficiency and profitability, as well as delivering a better patient experience from shorter cycle times and customer proximity. We have and may continue to financially invest in or explore collaborations with key ecosystem partners, including DSOs, whose missions and visions align with our own vision, strategy, business model and goals.

- 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 with 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 Invisalign treatment, in 2024, 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 United States. Similarly, in 2024, 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.
- 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 2024, 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.

Below is a discussion of the significant trends and uncertainties that could impact our operations:

#### *Macroeconomic Challenges and Military Conflicts in Ukraine and the Middle East*

Our revenues are susceptible to fluctuations resulting from events and circumstances, including macroeconomic conditions, fluctuations in foreign currency exchange rates, inflation, higher interest rates, actual and threatened wars and military actions, threats or actual imposition of tariffs, customs duties and fees by nations and retaliatory actions, threats of or actual slowdowns or recessions, supply chain challenges, market volatility, employment levels, wages, debt obligations, discretionary income 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. During 2024, we believe sales of our products were adversely impacted by macroeconomic conditions that negatively affected disposable income and consumer demand. We believe this trend will continue in 2025. We also expect the military conflict between Russia and Ukraine to continue to create market uncertainties and dampen consumer sentiment and demand, particularly in Europe.

Additionally, government actions in various countries relating to implemented or proposed tariffs, particularly the United States, China, Mexico, and Europe are expected to adversely impact our revenue and cost of goods sold if implemented. The degree of our exposure is dependent on, among other things, the type of goods subject to any tariffs enacted, the tariff rates imposed, the timing of the tariffs and any retaliatory measures enacted. The impact of declining demand may vary by time and region, making operational results uncertain and difficult to predict. We continue to closely monitor the foregoing issues, assess their potential impact on our operations and financial results, and implement plans to mitigate the impact of any adverse events.

Additionally, a material amount of our revenues are derived internationally and many of our international operations are denominated in currencies other than the U.S. dollar. In 2024, the U.S. dollar remained strong against major currencies, which negatively impacted our financial condition and results of operations for the year. Foreign exchange volatility and the subsequent strengthening or weakening of the U.S dollar against other currencies remains uncertain and unpredictable.

We continue to monitor the potential for violence and military actions that may directly or indirectly impact our personnel, manufacturing, supply chain, and sales. For instance, ongoing conflicts in the Middle East may further exacerbate general and regional macroeconomic instability, particularly if fighting intensifies, spreads to other locations, creates shipping and logistical challenges or cost increases, leads to sanctions or boycotts, or otherwise may materially impact our operations. For instance, our iTero business is headquartered in Israel and, although the sales, delivery times and cost of shipping our

products have not been materially impacted and we have put measures in place to help reduce the future risks, it remains uncertain if there will be impacts on our sales, delivery times or cost of shipping our products. While there have been export and import restrictions imposed against products originating from and businesses operating in Israel, they have not materially impacted our sales or operations to date although we continue to monitor the risk.

### *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 continue to anticipate customer and patient expectations and demands will continue to 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, tariffs and retaliatory measures, military conflicts and the evolution of our target markets, by focusing on improving our operations, further increasing flexibility and efficiencies in our processes, adjusting our business models to changing circumstances and offering products that meet market demand. Specifically, we are managing financial impacts through strategic product innovations, introductions and pricing actions, implementing cost saving measures and evaluating hiring needs.

As an example, there was significant adoption of the Invisalign Comprehensive 3in3 product after it was introduced in 2023 that continued in 2024. 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. The 3in3 product also allows us to recognize more revenue up front while doing so at a lower price as compared to our traditional Invisalign comprehensive product that has a five-year treatment expiration date with unlimited additional clear aligners 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***

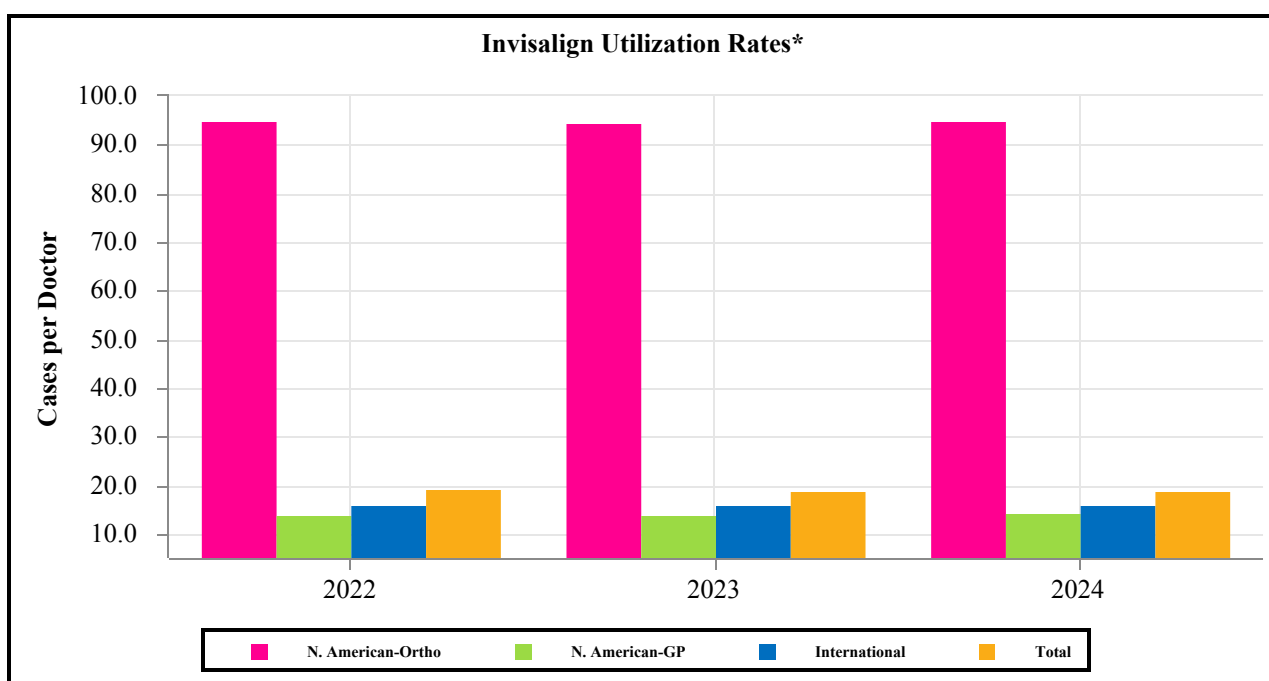
We measure our performance against these strategic priorities by the achievement of key financial and operating metrics. For the year ended December 31, 2024, our business operations reflect the following:

- Revenues of \$3,999.0 million, an increase of 3.5% year-over-year;
- Clear Aligner revenues of \$3,230.1 million, an increase of 1.0% year-over-year;
  - Americas Clear Aligner case revenues of \$1,426.3 million, a decrease of 2.5% year-over-year;
  - International Clear Aligner case revenues of \$1,500.5 million, an increase of 3.5% year-over-year;
  - Clear Aligner volume increase of 3.5% year-over-year and Clear Aligner volume increase for kids and teens of 7.7% year-over-year;
- Imaging Systems and computer-aided design and computer-aided manufacturing (“CAD/CAM”) Services revenues of \$768.9 million, an increase of 16.0% year-over-year;
- Income from operations of \$607.6 million and operating margin of 15.2%;
- Effective tax rate of 30.8%;
- Net income of \$421.4 million with diluted net income per share of \$5.62;
- Cash and cash equivalents of \$1,043.9 million as of December 31, 2024;
- Cash provided by operating activities of \$738.2 million;
- Capital expenditures of \$115.6 million, primarily related to investments in our manufacturing capacity and facilities; and
- Number of employees of 20,945 as of December 31, 2024, a decrease of 3.1% year-over-year.

### ***Other Statistical Data and Trends***

- As of December 31, 2024, over 19 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.

- The total number of Invisalign trained doctors cases were shipped to (doctor submitters) in 2024 was 130.4 thousand compared to 125.8 thousand in 2023, a 3.6% increase. GP and orthodontist doctor submitters increased by approximately 3% and 4%, respectively, in 2024 compared to 2023.
- Our total utilization rate in 2024 of 19.1 cases per doctor was flat compared to 2023 and slightly down from 19.3 cases per doctor in 2022. Our utilization rates have been impacted by 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 95.0 cases per doctor in 2024 compared to 94.5 cases per doctor in 2023 and 94.9 cases per doctor in 2022 and the utilization rate among our North American GP customers was 14.3 cases per doctor in 2024 compared to 14.0 cases per doctor in 2023 and 13.9 cases per doctor in 2022.
  - *International:* International doctor utilization rate was 16.2 cases per doctor in 2024 compared to 16.3 cases per doctor in 2023 and 16.2 cases per doctor in 2022.



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

## Results of Operations

### *Net Revenues by Reportable Segment*

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

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
  - Comprehensive Products include, but are not limited to, Invisalign Comprehensive, Invisalign First and Invisalign Comprehensive 3in3.
  - Non-Comprehensive Products include, but are not limited to, Invisalign Moderate, Lite and Express packages, Invisalign Go and Invisalign Go Plus and Invisalign Palatal Expander.



- In the United States, Canada, and EMEA, we also offer 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 revenues 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 sales related to our iTero intraoral scanning systems, which includes a single hardware platform and restorative or orthodontic software options, upgrades and leases of scanner systems, sales of pre-owned scanner systems, subscription software, disposables, 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, 2024, 2023 and 2022 are as follows (in millions):

	Year Ended December 31,				Year Ended December 31,			
Net Revenues	2024	2023	Change		2023	2022	Change	
Clear Aligner revenues:								
Americas	\$ 1,426.3	\$ 1,463.0	\$ (36.6)	(2.5)%	\$ 1,463.0	\$ 1,471.9	\$ (9.0)	(0.6)%
International	1,500.5	1,449.5	51.1	3.5 %	1,449.5	1,349.0	100.5	7.4 %
Non-case	303.3	286.9	16.4	5.7 %	286.9	251.7	35.2	14.0 %
Total Clear Aligner net revenues	\$ 3,230.1	\$ 3,199.3	\$ 30.8	1.0 %	\$ 3,199.3	\$ 3,072.6	\$ 126.7	4.1 %
Systems and Services net revenues	768.9	662.9	106.0	16.0 %	662.9	662.1	0.9	0.1 %
Total net revenues	\$ 3,999.0	\$ 3,862.3	\$ 136.8	3.5 %	\$ 3,862.3	\$ 3,734.6	\$ 127.6	3.4 %

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

### ***Clear Aligner Case Volume***

Case volume data which represents Clear Aligner case shipments for the year ended December 31, 2024, 2023 and 2022 is as follows (in thousands):

	Year Ended December 31,				Year Ended December 31,			
	2024	2023	Change		2023	2022	Change	
Total case volume	2,493.7	2,408.5	85.2	3.5 %	2,408.5	2,398.4	10.2	0.4 %

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

Total net revenues increased by \$137 million in 2024 as compared to 2023, primarily due to an increase in Systems and Services net revenues from higher scanner ASP, increase in non-system sales and services revenue. Clear Aligner net revenues increased primarily from an increase in volume, partially offset by lower Clear Aligner ASP.

### ***Clear Aligner - Americas***

Americas net revenues decreased by \$37 million in 2024 as compared to 2023, primarily due to a 3.0% decrease in ASP, resulting in a decrease of net revenues of \$44 million. The decrease in ASP was primarily driven by a mix shift to lower priced products and countries which reduced net revenues by \$88 million and higher promotional discounts which decreased net

revenues by \$66 million and unfavorable foreign exchange rates that decreased net revenues by \$9 million. These decreases were partially offset by lower net deferrals which increased net revenues by \$94 million and price changes which increased net revenues by \$19 million. The decrease in ASP was partially offset by an increase in volume which increased net revenues by \$7 million.

#### *Clear Aligner - International*

International net revenues increased by \$51 million in 2024 as compared to 2023 due to a 7.0% increase in volume, resulting in increased net revenues of \$101 million. This increase was partially offset by a decrease of 3.3% in ASP which decreased net revenues by \$50 million. Lower ASP was due to unfavorable foreign exchange rates that decreased net revenues by \$21 million and a price reduction for sales in the United Kingdom (“UK”) to offset VAT we began charging in 2024, which decreased net revenues by \$32 million, a mix shift to lower priced products and countries which reduced net revenues by \$60 million and higher promotional discounts which reduced net revenues by \$114 million. The decreases in ASP were partially offset by lower net deferrals and price changes which increased net revenues by \$99 million and \$72 million, respectively.

#### *Clear Aligner - Non-Case*

Non-case net revenues increased by \$16 million in 2024 compared to 2023 mainly due to increased volume of Vivera retainers which includes retention aligners ordered through our Doctor Subscription Program.

#### *Systems and Services*

Systems and Services net revenues increased by \$106 million in 2024 as compared to 2023 primarily due to higher scanner ASP which increased net revenues by \$45 million, an increase in sales of upgrade scanner systems which increased net revenues by \$38 million, higher services revenue which increased net revenues by \$19 million and higher volume which increased net revenues by \$4 million. Additionally, CAD/CAM software revenues increased net revenues by \$7 million. These increases were partially offset by unfavorable foreign exchange rates which decreased net revenues by \$7 million.

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

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
<b><u>Clear Aligner</u></b>						
Cost of net revenues	\$ 952.1	\$ 911.3	\$ 40.8	\$ 911.3	\$ 844.4	\$ 66.9
% of net segment revenues	29.5 %	28.5 %		28.5 %	27.5 %	
Gross profit	\$ 2,278.0	\$ 2,288.0	\$ (10.1)	\$ 2,288.0	\$ 2,228.2	\$ 59.9
Gross margin %	70.5 %	71.5 %		71.5 %	72.5 %	
<b><u>Systems and Services</u></b>						
Cost of net revenues	\$ 247.7	\$ 244.1	\$ 3.6	\$ 244.1	\$ 256.4	\$ (12.3)
% of net segment revenues	32.2 %	36.8 %		36.8 %	38.7 %	
Gross profit	\$ 521.2	\$ 418.8	\$ 102.3	\$ 418.8	\$ 405.6	\$ 13.2
Gross margin %	67.8 %	63.2 %		63.2 %	61.3 %	
<b><u>Total cost of net revenues</u></b>	<b>\$ 1,199.9</b>	<b>\$ 1,155.4</b>	<b>\$ 44.5</b>	<b>\$ 1,155.4</b>	<b>\$ 1,100.9</b>	<b>\$ 54.5</b>
<b><u>% of net revenues</u></b>	<b>30.0 %</b>	<b>29.9 %</b>		<b>29.9 %</b>	<b>29.5 %</b>	
Gross profit	\$ 2,799.2	\$ 2,706.9	\$ 92.3	\$ 2,706.9	\$ 2,633.8	\$ 73.1
Gross margin %	70.0 %	70.1 %		70.1 %	70.5 %	

*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, 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 2024 as compared to 2023 primarily due to lower ASPs and higher restructuring expense.

## Systems and Services

The gross margin percentage increased in 2024 as compared to 2023 primarily due to higher ASPs and lower cost of net revenues leverage, partially offset by lower service revenue mix.

### ***Selling, general and administrative (in millions):***

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
Selling, general and administrative	\$ 1,763.2	\$ 1,703.4	\$ 59.8	\$ 1,703.4	\$ 1,674.5	\$ 28.9
% of net revenues	44.1 %	44.1 %		44.1 %	44.8 %	

*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 2024 compared to 2023 primarily due to higher employee costs, including salaries, fringe benefits, stock-based compensation and bonus partially offset by lower outside services expense.

### ***Research and development (in millions):***

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
Research and development	\$ 364.2	\$ 346.8	\$ 17.4	\$ 346.8	\$ 305.3	\$ 41.6
% of net revenues	9.1 %	9.0 %		9.0 %	8.2 %	

*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 2024 compared to 2023 primarily due to higher employee costs, including salaries, fringe benefits, stock-based compensation, net of capitalized labor costs related to internal use software, and bonus, partially offset by lower outside services expense.

### ***Restructuring and other charges (in millions):***

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
Restructuring and other charges	\$ 33.2	\$ 13.3	\$ 19.9	\$ 13.3	\$ 11.5	\$ 1.9
% of net revenues	0.8 %	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 increased in 2024 compared to 2023 due to higher severance and other one-time post-employment benefits, driven by a more significant restructuring plan initiated in 2024. Refer to Note 17 “Restructuring and Other Charges” of the Notes to Consolidated Financial Statements for more information.

**Legal settlement loss (in millions):**

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
Legal settlement loss	\$ 31.0	\$ —	\$ 31.0	\$ —	\$ —	\$ —
% of net revenues	0.8 %	— %		— %	— %	

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

Legal settlement loss incurred during 2024 was due to litigation and other settlements. Refer to Note 8 “Legal Proceedings” of the Notes to Consolidated Financial Statements for more information.

**Income from operations (in millions):**

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
<b>Clear Aligner</b>						
Income from operations	\$ 1,142.2	\$ 1,182.3	\$ (40.1)	\$ 1,182.3	\$ 1,134.4	\$ 47.8
Operating margin %	35.4 %	37.0 %		37.0 %	36.9 %	
<b>Systems and Services</b>						
Income from operations	\$ 269.2	\$ 191.4	\$ 77.9	\$ 191.4	\$ 179.8	\$ 11.6
Operating margin %	35.0 %	28.9 %		28.9 %	27.2 %	
<b>Total Income from operations</b> <sup>1</sup>	\$ 607.6	\$ 643.3	\$ (35.7)	\$ 643.3	\$ 642.6	\$ 0.7
Operating margin %	15.2 %	16.7 %		16.7 %	17.2 %	

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

<sup>1</sup> Refer to Note 16 “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.

Total operating margin percentage decreased in 2024 compared to 2023 primarily due to increased legal settlement losses, restructuring and other charges and employee costs. Refer to Note 8 “Legal Proceedings” of the Notes to Consolidated Financial Statements.

**Clear Aligner**

Operating margin percentage decreased in 2024 compared to 2023 primarily due to a decrease in gross margin and an increase in employee costs.

**Systems and Services**

Operating margin percentage increased in 2024 compared to 2023 primarily due to higher gross margin, partially offset by an increase in employee costs.

**Interest income (in millions):**

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
Interest income	\$ 20.2	\$ 17.3	\$ 3.0	\$ 17.3	\$ 5.4	\$ 11.9
% of net revenues	0.5 %	0.4 %		0.4 %	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 2024 compared to 2023 primarily due to primarily due to higher cash and cash equivalents.

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

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
Other income (expense), net	\$ (18.9)	\$ (19.4)	\$ 0.5	\$ (19.4)	\$ (48.9)	\$ 29.5
% of net revenues	(0.5)%	(0.5)%		(0.5)%	(1.3)%	

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 increased in 2024 compared to 2023 primarily due to gains recorded on our equity investments, offset by the unfavorable impact of foreign exchange rates.

**Provision for income taxes (in millions):**

	Year Ended December 31,			Year Ended December 31,		
	2024	2023	Change	2023	2022	Change
Provision for (benefit from) income taxes	\$ 187.6	\$ 196.2	\$ (8.6)	\$ 196.2	\$ 237.5	\$ (41.3)
Effective tax rates	30.8 %	30.6 %		30.6 %	39.6 %	

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

The increase in our effective tax rate for the year ended December 31, 2024 compared to the same period in 2023 is primarily attributable to an increase in U.S. taxes on foreign earnings, partially offset by a change in our jurisdictional mix of income and release of unrecognized tax benefits due to a lapse of the statute of limitation.

**Liquidity and Capital Resources***Liquidity and Trends*

As of December 31, 2024 and 2023, we had the following cash and cash equivalents and short-term and long-term marketable securities (in thousands):

	December 31,	
	2024	2023
Cash and cash equivalents	\$ 1,043,887	\$ 937,438
Marketable securities, short-term	—	35,304
Marketable securities, long-term	—	8,022
Total	<u>\$ 1,043,887</u>	<u>\$ 980,764</u>

As of December 31, 2024 and 2023, approximately \$855 million and \$785 million, respectively, of cash, cash equivalents and marketable securities were held by our foreign subsidiaries. We continue to evaluate opportunities to repatriate our foreign earnings if or when needed. We 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 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, 2024 are as follows:

- 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 \$1,193 million. We anticipate a majority, an estimated \$1,003 million, will be payable within the next 12 months. These purchase commitments exclude capital expenditures.
- We expect our investments in capital expenditures to be between \$100 million and \$150 million for the next 12 months. Capital expenditures primarily relate to building construction and improvements as well as additional manufacturing capacity. 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 demand.

- We have future operating lease payments of \$133 million, which includes \$2.6 million for leases that have not yet commenced as of December 31, 2024. Refer to *Note 4 “Leases” of the Notes to Consolidated Financial Statements* for details on the lease payments.
- We have approximately \$297 million, inclusive of approximately \$72 million repurchased in January 2025, 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 11 “Common Stock Repurchase Programs” of the Notes to Consolidated Financial Statements* for details on our stock repurchase activity.
- In 2024, we agreed, in principle, to settle certain legal matters. As of December 31, 2024, a total of \$27.5 million remained unpaid. Settlement payments will be made in accordance with the terms and conditions as set forth in the settlement agreement. Refer to *Note 8 “Legal Proceedings” of the Notes to Consolidated Financial Statements* for more information.
- As of December 31, 2024, 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 Uses of Cash*

The following table summarizes our Consolidated Statements of Cash Flows for the year ended December 31, 2024, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Net cash provided by (used in):			
Operating activities	\$ 738,231	\$ 785,776	\$ 568,732
Investing activities	(254,912)	(195,943)	(213,316)
Financing activities	(355,722)	(598,340)	(501,686)
Effects of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(21,153)	4,671	(11,514)
Net (decrease) increase in cash, cash equivalents, and restricted cash	<u>\$ 106,444</u>	<u>\$ (3,836)</u>	<u>\$ (157,784)</u>

### **Operating Activities**

For the year ended December 31, 2024, cash flows from operations of \$738 million resulted primarily from our net income of approximately \$421 million as well as the following:

#### *Significant adjustments to net income*

- Stock-based compensation of \$174 million related to equity awards granted to employees and directors; and
- Depreciation and amortization of \$145 million related to our investments in property, plant and equipment and intangible assets.

#### *Significant changes in working capital*

- Net inflow of \$90 million from accrued and other long-term liabilities primarily due to timing of payments;
- Net inflow of \$68 million from prepaid expenses and other assets primarily due to settlement of tax matter. Refer to *Note 8 “Legal Proceedings” of the Notes to Consolidated Financial Statements*.
- Net outflow of \$80 million from deferred revenues; and
- Net outflow of \$153 million from accounts receivable due to timing of collections and increased revenues.

For the year ended December 31, 2023, cash flows from operations of \$786 million resulted primarily from our net income of approximately \$445 million as well as the following:

*Significant adjustments to net income*

- Stock-based compensation of \$154 million related to equity awards granted to employees and directors; and
- Depreciation and amortization of \$142 million related to our investments in property, plant and equipment and intangible assets.

*Significant changes in working capital*

- Net inflow of \$46 million from accrued and other long-term liabilities primarily due to higher incentive accruals for 2023, as well as timing of payments of other activities;
- Net inflow of \$87 million from deferred revenues due to the deferral of revenue on shipments;
- Net inflow of \$30 million from inventories primarily due to lower purchases of materials used in manufacturing; and
- Net outflow of \$105 million, net from accounts receivable due to timing of collections and increased revenues.

**Investing Activities**

Net cash used in investing activities was \$255 million for the year ended December 31, 2024 which primarily consisted of \$116 million for purchases of property, plant and equipment, \$77 million for the Cubicure acquisition and \$106 million for investments in privately held companies, partially offset by sales and maturities of marketable securities of \$44 million.

Net cash used in investing activities was \$196 million for the year ended December 31, 2023 which primarily consisted of purchases of property, plant and equipment of \$178 million which included a building acquisition for \$25 million, an investment in equity of a privately held company of \$77 million and purchases of marketable securities of \$3 million, partially offset by sales and maturities of marketable securities of \$61 million.

**Financing Activities**

Net cash used in financing activities was \$356 million for the year ended December 31, 2024 which consisted of payments to repurchase shares of our common stock of \$353 million and payroll taxes paid for equity awards through share withholdings of \$28 million, which were partially offset by proceeds from the issuance of common stock for \$25 million.

Net cash used in financing activities was \$598 million for the year ended December 31, 2023 which consisted of payments to repurchase shares of our common stock of \$602 million and payroll taxes paid for equity awards through share withholdings of \$23 million, which were partially offset by proceeds from the issuance of common stock for \$27 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. Sales contracts with multiple performance obligations require management to exercise judgment in allocating the transaction price, based on standalone selling prices, to each performance obligation and determining the timing of revenue recognition which directly impacts our unfulfilled performance obligations at period end.

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 \$1,444.9 million and \$1,578.3 million as of December 31, 2024 and 2023, 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 (“DCF”) analysis and allocate our net assets to each reporting unit to determine carrying value. The use of a DCF model requires management to exercise significant judgement related to operating assumptions and estimates including, revenue growth rates, terminal growth rates, operating margins and discount rates, among others. Additionally, management exercises judgement when determining the methodology used to allocate net assets to each reporting unit. We will record an impairment charge when our quantitative impairment analysis indicates that the carrying value of a reporting unit exceeds its fair value.

### ***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 that are greater 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 year ended 2024 and 2023, 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 United States 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. 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 in the jurisdictions in which we operate. 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. We may, in the future, be required to increase the valuation allowance to take into account additional deferred tax assets that we may be unable to realize.

### ***Accounting for Legal Proceedings***

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 that are difficult to predict and, therefore, the ultimate cost to resolve such matters may be materially different than our 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 Part I, 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 earned on our cash and cash equivalents balance. As of December 31, 2024, we are not exposed to interest rate risk on our unsecured revolving line of credit. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We have not historically used derivative financial instruments to manage our exposure to changes in interest rates.

#### ***Foreign Currency Exchange Rate Risk***

As a result of our international business activities, our financial results have been affected by changes in foreign currency exchange rates as well as economic conditions in foreign markets. There is no assurance that exchange rate fluctuations will not adversely impact our results of operations or financial condition 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 also 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 certain assets and liabilities. 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.

Although we will continue to monitor our exposure to currency fluctuations, and, where appropriate, 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. If our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. There is no assurance that our results of operations and financial condition will not be adversely impacted by inflation in the future.

**Item 8. Financial Statements and Supplementary Data.**

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## MANAGEMENT’S ANNUAL REPORT 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, as amended. 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. 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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. 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, 2024, 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, 2024 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

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**Joseph M. Hogan**

*President and Chief Executive Officer*

February 28, 2025

/s/ JOHN F. MORICI

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**John F. Morici**

*Chief Financial Officer and Executive Vice President, Global Finance*

February 28, 2025

## **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, 2024 and 2023, 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, 2024, including the related notes and schedule of Valuation and Qualifying Accounts and Reserves for each of the three years in the period ended December 31, 2024 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 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, 2024, 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 Management's Annual Report 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 16 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, 2024. 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 relating 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, 2025

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,		
	2024	2023	2022
Net revenues	\$ 3,999,012	\$ 3,862,260	\$ 3,734,635
Cost of net revenues	1,199,853	1,155,397	1,100,860
Gross profit	2,799,159	2,706,863	2,633,775
Operating expenses:			
Selling, general and administrative	1,763,193	1,703,379	1,674,469
Research and development	364,202	346,830	305,258
Restructuring and other charges	33,168	13,316	11,453
Legal settlement loss	30,968	—	—
Total operating expenses	2,191,531	2,063,525	1,991,180
Income from operations	607,628	643,338	642,595
Interest income and other income (expense), net:			
Interest income	20,218	17,258	5,367
Other income (expense), net	(18,887)	(19,392)	(48,905)
Total interest income and other income (expense), net	1,331	(2,134)	(43,538)
Net income before provision for income taxes	608,959	641,204	599,057
Provision for income taxes	187,597	196,151	237,484
Net income	<u>\$ 421,362</u>	<u>\$ 445,053</u>	<u>\$ 361,573</u>
Net income per share:			
Basic	<u>\$ 5.63</u>	<u>\$ 5.82</u>	<u>\$ 4.62</u>
Diluted	<u>\$ 5.62</u>	<u>\$ 5.81</u>	<u>\$ 4.61</u>
Shares used in computing net income per share:			
Basic	<u>74,877</u>	<u>76,426</u>	<u>78,190</u>
Diluted	<u>74,993</u>	<u>76,568</u>	<u>78,420</u>

*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,		
	2024	2023	2022
Net income	\$ 421,362	\$ 445,053	\$ 361,573
Other comprehensive income (loss):			
Change in foreign currency translation adjustment, net of tax	(15,786)	28,419	(11,480)
Change in unrealized gains (losses) on investments, net of tax	596	3,033	(3,130)
Other comprehensive income (loss)	(15,190)	31,452	(14,610)
Comprehensive income	<u>\$ 406,172</u>	<u>\$ 476,505</u>	<u>\$ 346,963</u>

*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,	
	2024	2023
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,043,887	\$ 937,438
Marketable securities, short-term	—	35,304
Accounts receivable, net of allowance for doubtful accounts of \$19,131 and \$14,893, respectively	995,685	903,424
Inventories	254,287	296,902
Prepaid expenses and other current assets	198,582	273,550
Total current assets	2,492,441	2,446,618
Marketable securities, long-term	—	8,022
Property, plant and equipment, net	1,271,134	1,290,863
Operating lease right-of-use assets, net	113,376	117,999
Goodwill	442,630	419,530
Intangible assets, net	103,488	82,118
Deferred tax assets	1,557,372	1,590,045
Other assets	234,159	128,682
Total assets	<u>\$ 6,214,600</u>	<u>\$ 6,083,877</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 108,693	\$ 113,125
Accrued liabilities	598,188	525,780
Deferred revenues	1,331,146	1,427,706
Total current liabilities	2,038,027	2,066,611
Income tax payable	96,466	116,744
Operating lease liabilities	88,214	96,968
Other long-term liabilities	139,908	173,065
Total liabilities	2,362,615	2,453,388
Commitments and contingencies (Notes 8 and 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued)	—	—
Common stock, \$0.0001 par value (200,000 shares authorized; 73,849 and 75,075 issued and outstanding, respectively)	7	7
Additional paid-in capital	1,362,234	1,162,140
Accumulated other comprehensive income (loss), net	5,978	21,168
Retained earnings	2,483,766	2,447,174
Total stockholders' equity	3,851,985	3,630,489
Total liabilities and stockholders' equity	<u>\$ 6,214,600</u>	<u>\$ 6,083,877</u>

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

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

	<b>Common Stock</b>		<b>Additional Paid-In Capital</b>	<b>Accumulated Other Comprehensive Income (Loss), Net</b>	<b>Retained Earnings</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>				
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 <sup>1</sup>	305	—	26,149	—	—	26,149
Tax withholdings related to net share settlements of equity awards	—	—	(52,799)	—	—	(52,799)
Common stock repurchased and retired	(1,748)	—	(20,777)	—	(414,259)	(435,036)
Equity forward contract related to accelerated stock repurchase	—	—	(40,000)	—	—	(40,000)
Stock-based compensation	—	—	133,367	—	—	133,367
Balance as of December 31, 2022	77,267	8	1,044,946	(10,284)	2,566,688	3,601,358
Net income	—	—	—	—	445,053	445,053
Net change in unrealized gains (losses) from investments	—	—	—	3,033	—	3,033
Net change in foreign currency translation adjustment	—	—	—	28,419	—	28,419
Issuance of common stock relating to employee equity compensation plans	335	—	26,595	—	—	26,595
Tax withholdings related to net share settlements of equity awards	(70)	—	(22,575)	—	—	(22,575)
Common stock repurchased and retired	(2,457)	(1)	(30,852)	—	(564,567)	(595,420)
Equity forward contract related to accelerated stock repurchase	—	—	(10,000)	—	—	(10,000)
Stock-based compensation	—	—	154,026	—	—	154,026
Balance as of December 31, 2023	75,075	7	1,162,140	21,168	2,447,174	3,630,489
Net income	—	—	—	—	421,362	421,362
Net change in unrealized gains (losses) from investments	—	—	—	596	—	596
Net change in foreign currency translation adjustment	—	—	—	(15,786)	—	(15,786)
Issuance of common stock relating to employee equity compensation plans	411	—	25,281	—	—	25,281
Tax withholdings related to net share settlements of equity awards	(92)	—	(28,125)	—	—	(28,125)
Common stock repurchased and retired	(1,545)	—	(20,292)	—	(335,243)	(355,535)
Equity forward contract related to accelerated stock repurchase	—	—	49,527	—	(49,527)	—
Stock-based compensation	—	—	173,703	—	—	173,703
Balance as of December 31, 2024	73,849	\$ 7	\$1,362,234	\$ 5,978	\$2,483,766	\$ 3,851,985

<sup>1</sup> Includes tax withholding shares related to net share settlements of equity awards.

*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,		
	2024	2023	2022
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 421,362	\$ 445,053	\$ 361,573
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred taxes	25,756	(18,642)	(39,495)
Depreciation and amortization	145,034	142,401	125,793
Stock-based compensation	173,703	154,026	133,367
Non-cash operating lease cost	38,438	33,107	30,520
Impairments and fair value adjustments for equity investments	(5,885)	4,990	—
Other non-cash operating activities	12,256	32,733	41,288
Changes in assets and liabilities, net of effects of acquisitions:			
Accounts receivable	(153,487)	(104,614)	21,549
Inventories	25,053	30,169	(130,097)
Prepaid expenses and other assets	67,527	(51,013)	(65,514)
Accounts payable	(843)	(7,703)	(36,523)
Accrued and other long-term liabilities	89,705	46,327	(121,942)
Long-term income tax payable	(20,279)	(7,772)	6,327
Deferred revenues	(80,109)	86,714	241,886
Net cash provided by operating activities	738,231	785,776	568,732
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Acquisitions, net of cash acquired	(77,075)	—	(12,304)
Purchase of property, plant and equipment	(115,580)	(177,716)	(291,900)
Purchase of marketable securities	—	(2,910)	(28,002)
Proceeds from maturities of marketable securities	25,660	55,170	23,785
Proceeds from sales of marketable securities	18,193	6,234	97,316
Purchase of equity investments	(106,345)	(76,999)	—
Other investing activities	235	278	(2,211)
Net cash used in investing activities	(254,912)	(195,943)	(213,316)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock	25,281	26,595	26,149
Common stock repurchases	(352,878)	(592,360)	(435,036)
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	(28,125)	(22,575)	(52,799)
Net cash used in financing activities	(355,722)	(598,340)	(501,686)
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash	(21,153)	4,671	(11,514)
Net (decrease) increase in cash, cash equivalents, and restricted cash	106,444	(3,836)	(157,784)
Cash, cash equivalents, and restricted cash at beginning of year	938,519	942,355	1,100,139
Cash, cash equivalents, and restricted cash at end of year	<u>\$1,044,963</u>	<u>\$ 938,519</u>	<u>\$ 942,355</u>

*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,” “us,” “our,” “Align” or the “Company”) is a global medical device company primarily engaged in the design, manufacture and marketing of Invisalign<sup>®</sup> clear aligners for the treatment of malocclusions, or the misalignment of teeth, by orthodontists and general dental practitioners (“GPs”), Vivera<sup>™</sup> retainers for retention, iTero<sup>™</sup> intraoral scanners and services for dentistry, and exocad<sup>™</sup> 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 the Align<sup>™</sup> 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<sup>™</sup> 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 iTero 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 and (2) Imaging Systems and CAD/CAM services (“Systems and 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 and deferred revenues, useful lives of intangible assets and property, plant and equipment, goodwill, income taxes, contingent liabilities, the fair values of financial instruments, stock-based compensation and the valuation of investments in privately held companies among others. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

***Fair Value of Financial Instruments***

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

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

*Level 2* - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. We obtain fair values for our Level 2 investments. Our custody bank and asset managers independently use professional pricing services to gather pricing data which may include quoted market prices for identical or comparable financial instruments, or inputs other than quoted prices that are observable either directly or indirectly. 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 Statements of Operations. If we have an intent to sell, or if it is more likely than not that we will be required to sell a 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 Statements of Operations.

As of December 31, 2024 we have no short term or long term marketable securities.

### ***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 assets, liabilities, income and expense of the VIE into our consolidated 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 activities that are significant to the VIE and an assessment of our ability to direct those activities. Our assessment of whether we are the primary beneficiary of a VIE requires 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 investments 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 at cost, minus impairment, if any. Additionally, we adjust the carrying value of our investments for observable transactions for identical or similar investments of the same issuer.

On April 24, 2023 and April 22, 2024, we entered into Subscription Agreements (the "Heartland Subscription Agreements") with Heartland Dental Holding Corporation ("Heartland"). Pursuant to the Heartland Subscription Agreements we acquired less than a 5% equity interest in total, through the purchase of Class A Common Stock for \$150 million (\$75 million in each April 2023 and April 2024).

On December 19, 2024, we entered into a Subscription Agreement (the “Smile Doctors Subscription Agreement”) with New SD Holding Company, L.P. (“SD Holding Company”). Pursuant to the Smile Doctors Subscription Agreement we acquired less than a 3% equity interest through the purchase of Class A Common Units for \$30 million. SD Holding Company owns a controlling interest, through intermediary entities, in Smile Doctors, LLC.

We account for our investments in Heartland and SD Holding Company as investments in equity securities, utilizing the measurement alternative. Based on a review of the relevant facts and circumstances, primarily observable transactions for identical investments, we recorded a \$6 million increase to the carrying value of our investment in Heartland for the year ended December 31, 2024. We did not record an adjustment for the year ended December 31, 2023.

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 investments in equity securities and equity method investments are reported in our Consolidated Balance Sheets as other assets and any fair value adjustments or impairment, if any, are recorded in other income (expense), net in our Consolidated Statements of Operations.

### ***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 Statements 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, 2024, 2023 and 2022, we had foreign currency transaction losses of \$21.0 million, \$7.0 million and \$43.8 million, respectively.

### ***Certain Risks and Uncertainties***

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 collection history. 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, 2024 or 2023 nor net revenues for the year ended December 31, 2024, 2023 or 2022.

For the year ended December 31, 2024 and 2023, 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 \$52.1 million and \$51.2 million during the year ended December 31, 2024, and 2023, 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 lease liability balance. The short-term portion of our lease liabilities is recorded in accrued liabilities on our Consolidated Balance Sheets.

### ***Leases - Lessor***

We determine if an arrangement is or contains a lease at inception. All of our leases in which we are the lessor are classified as operating leases, exclusive of leases with a term of 12 months or less. The underlying asset in an operating lease arrangement is carried at depreciated cost within Property, plant, and equipment, net 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, particularly with respect to determining the fair value of intangible assets. The estimates and assumptions used in fair valuing intangible assets include, but are not limited to, the amount and timing of projected future cash flows which are dependent on forecasted revenues and expenses, a discount rate, and the assets' life cycle, among others. 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. The average amortization period by intangible asset class ranges from ten to twelve years. This amortization period reflects 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, 2024 or 2023.

### ***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 Statements 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 identify separate performance obligations, determine the transaction price, allocate the transaction price and record revenue in accordance with ASC 606 *“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 the transaction price 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 and the option of additional aligners. We allocate the transaction price 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 revenue upon shipment, as the customers obtain physical possession and we have enforceable rights to payment. We have made an accounting policy election to account for 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 transaction price.

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, an 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 services. 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 \$25.8 million and \$25.1 million as of December 31, 2024 and 2023, respectively, and are included in other assets in our Consolidated Balance Sheets. We recognized amortization on our costs to obtain a contract of \$18.7 million, \$12.5 million, and \$20.8 million during the year ended December 31, 2024, 2023, and 2022, 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 \$1,444.9 million and \$1,578.3 million as of December 31, 2024 and 2023, 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 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*

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

#### *Research and Development*

Research and development costs are expensed as incurred and include costs associated with the research and development of new products and enhancements to existing products. These costs primarily include employee related costs, including payroll, benefits 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, 2024, 2023 and 2022, we incurred advertising costs of \$185.0 million, \$201.2 million and \$222.0 million, respectively.

#### *Stock-Based Compensation*

We recognize stock-based compensation cost for shares expected to vest on a straight-line basis over the requisite service period of the award, net of estimated forfeitures. We use the Black-Scholes option pricing model to determine the fair value of employee stock purchase plan shares. We use a Monte Carlo simulation model to estimate the fair value of awards with a market based condition which requires the input of assumptions, including expected term, stock price volatility and the risk-free rate of return. For restricted stock units that include a performance condition, 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 Statements 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***

On November 27, 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07 (“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 and other 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. We adopted this standard in the fiscal year ended December 31, 2024. *Note 16 “Segments and Geographical Information” of the Notes of Consolidated Financial Statements*

#### ***(ii) Recent Accounting Pronouncements Not Yet Effective***

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. There will be no impact to our consolidated balance sheets or statements of operations; however, the Company is evaluating the effect of this pronouncement on our consolidated financial statement disclosures.

On November 4, 2024, the FASB issued ASU 2024-03, *“Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures.”* The amendments in this ASU require a public entity to disclose, in the notes to the financial statements, specified information about certain costs and expenses, including the amounts of inventory purchases, employee compensation, depreciation and intangible asset amortization. For public business entities, the provisions of ASU 2024-03 are effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. There will be no impact to our consolidated balance sheets or statements of operations; however, the Company is evaluating the effect of this pronouncement on our consolidated financial statement disclosures.

## **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, 2024 and 2023 (in thousands):

December 31, 2024	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	\$ 752,423	\$ —	\$ —	\$ 752,423	\$ 752,423	\$ —	\$ —
Money market funds	291,464	—	—	291,464	291,464	—	—
Total	<u>\$1,043,887</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,043,887</u>	<u>\$1,043,887</u>	<u>\$ —</u>	<u>\$ —</u>

We have no short-term or long-term marketable securities as of December 31, 2024.

December 31, 2023	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	\$ 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	<u>\$ 981,569</u>	<u>\$ 7</u>	<u>\$ (812)</u>	<u>\$ 980,764</u>	<u>\$ 937,438</u>	<u>\$ 35,304</u>	<u>\$ 8,022</u>

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

	December 31, 2023
Due in 1 year or less	\$ 34,617
Due in 1 year through 5 years	8,709
Total	<u>\$ 43,326</u>

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

The following table summarizes the gross unrealized losses as of December 31, 2023, aggregated by investment category and length of time that individual securities have been in a continuous loss position (in thousands):

December 31, 2023	As of December 31, 2023					
	Less than 12 months		12 Months or Greater		Total	
	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	<u>\$ 7,065</u>	<u>\$ (23)</u>	<u>\$ 32,612</u>	<u>\$ (789)</u>	<u>\$ 39,677</u>	<u>\$ (812)</u>

## ***Fair Value Measurements***

The following tables summarize our financial assets measured at fair value and categorized by fair value hierarchy as of December 31, 2024 and 2023 (in thousands):

Description	Balance as of December 31, 2024	Level 1	Level 2
<b>Cash equivalents:</b>			
Money market funds	\$ 291,464	\$ 291,464	\$ —
	<u>\$ 291,464</u>	<u>\$ 291,464</u>	<u>\$ —</u>

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

We had no financial assets that were categorized as level 3 in the fair value hierarchy for the year ended December 31, 2024 or 2023.

## ***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 gain of \$35.2 million during the year ended December 31, 2024. We recognized a net loss of \$15.9 million during the year ended December 31, 2023 and the net gain recognized during the year ended December 31, 2022 was not material. As of December 31, 2024 and 2023, 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, 2024 and 2023 (in thousands):

	December 31, 2024	
	Local Currency Amount	Notional Contract Amount (USD)
Euro	€176,080	\$ 183,172
Polish Zloty	PLN283,000	68,633
Canadian Dollar	C\$97,000	67,446
British Pound	£37,600	47,090
Israeli Shekel	ILS90,055	24,740
Chinese Yuan	¥164,500	22,417
Brazilian Real	R\$83,100	13,327
Japanese Yen	¥2,000,000	12,778
Swiss Franc	CHF5,700	6,314
New Zealand Dollar	NZ\$7,000	3,924
Czech Koruna	Kč72,800	3,004
Australian Dollar	A\$3,800	2,355
New Taiwan Dollar	NT\$58,700	1,786
Korean Won	₩2,000,000	1,361
		<u>\$ 458,347</u>

	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
		<u>\$ 744,462</u>

### Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	\$ 124,377	\$ 145,492
Work in progress	73,660	91,259
Finished goods	56,250	60,151
Total inventories	<u>\$ 254,287</u>	<u>\$ 296,902</u>

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

	December 31,	
	2024	2023
Value added tax receivables <sup>1</sup>	\$ 34,028	\$ 143,728
Prepaid expenses	82,978	52,487
Other current assets	81,576	77,335
Total prepaid expenses and other current assets	<u>\$ 198,582</u>	<u>\$ 273,550</u>

<sup>1</sup> Refer to Note 9 “Commitments and Contingencies” of the Notes to Consolidated Financial Statements for discussion of tax matter.

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

	Generally Used Estimated Useful Life	December 31,	
		2024	2023
Clinical and manufacturing equipment	Up to 13 years	\$ 871,827	\$ 703,805
Building	20 years	529,716	517,554
Leasehold improvements	Lease term <sup>1</sup>	62,172	62,216
Computer software and hardware	3 years	135,756	125,633
Land	—	63,875	63,875
Furniture, fixtures and other	2-5 years	135,816	122,820
Construction in progress	—	133,684	245,722
Total		<u>1,932,846</u>	<u>1,841,625</u>
Less: Accumulated depreciation and impairment charges		<u>(661,712)</u>	<u>(550,762)</u>
Total property, plant and equipment, net		<u>\$ 1,271,134</u>	<u>\$ 1,290,863</u>

<sup>1</sup> Shorter of the remaining lease term or the estimated useful lives of the assets.

Depreciation was \$126.2 million, \$126.0 million and \$109.8 million for the year ended December 31, 2024, 2023 and 2022, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2024	2023
Accrued payroll and benefits	\$ 248,003	\$ 220,862
Accrued expenses	66,391	71,109
Accrued income taxes	48,808	38,103
Accrued sales and marketing expenses	37,617	34,035
Current operating lease liabilities	31,063	29,651
Accrued property, plant and equipment	13,462	23,618
Other accrued liabilities	152,844	108,402
Total accrued liabilities	<u>\$ 598,188</u>	<u>\$ 525,780</u>



Accrued warranty as of December 31, 2024 and 2023, 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, 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
Charged to cost of net revenues		21,962
Actual warranty expenditures		(13,177)
Accrued warranty as of December 31, 2024	\$	31,211

Deferred revenues consist of the following (in thousands):

	December 31,	
	2024	2023
Deferred revenues - current	\$ 1,331,146	\$ 1,427,706
Deferred revenues - long-term <sup>1</sup>	102,164	138,000

<sup>1</sup> Included in Other long-term liabilities within our Consolidated Balance Sheets.

During the year ended December 31, 2024 and 2023, we recognized \$3,999.0 million and \$3,862.3 million of net revenues, respectively, of which \$819.0 million and \$732.4 million was included in the deferred revenues balance at December 31, 2023 and December 31, 2022, 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 expense consist of following (in thousands):

Lease Cost	Year Ended December 31,		
	2024	2023	2022
Operating lease cost <sup>1</sup>	\$ 42,299	\$ 44,614	\$ 37,919
Variable lease cost <sup>2</sup>	3,630	16,013	22,084
Total lease cost	\$ 45,929	\$ 60,627	\$ 60,003

<sup>1</sup> Includes expense associated with short term leases, lease terms of 12 months or less, which is not material.

<sup>2</sup> Includes payments related to agreements with embedded leases that are not otherwise reflected on the balance sheet.

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

Remaining Lease Term and Discount Rate	December 31,	
	2024	2023
Weighted average remaining lease term (in years)	5.4	6.2
Weighted average discount rate	3.8 %	3.7 %

As of December 31, 2024, the future payments related to our operating lease liabilities are as follows (in thousands):

<b>Fiscal Year Ending December 31,</b>	<b>Operating Leases</b>
2025	\$ 35,195
2026	30,857
2027	22,103
2028	16,624
2029	10,225
Thereafter	15,517
Total lease payments	130,521
Less: Imputed interest	(11,244)
Total lease liabilities	<u>\$ 119,277</u>

As of December 31, 2024, we had additional leases that had not commenced with future lease payments of \$2.6 million. These leases will commence during 2025 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:

	<b>December 31,</b>	
	<b>2024</b>	<b>2023</b>
Scanners under operating leases, gross	\$ 33,770	\$ 27,145
Less: accumulated depreciation	(12,038)	(9,815)
Scanners under operating leases, net	<u>\$ 21,732</u>	<u>\$ 17,330</u>

As of December 31, 2024, the future lease payments due to us are as follows (in thousands):

<b>Fiscal Year Ending December 31,</b>	<b>Operating Leases</b>
2025	\$ 24,797
2026	16,296
2027	5,865
Total lease payments	<u>\$ 46,958</u>

For the year ended December 31, 2024, 2023 and 2022, operating lease income was \$21.7 million, \$16.6 million and \$12.3 million, respectively. Operating lease income is recorded in net revenues in our Consolidated Statements of Operations.

### **Note 5. Business Combination**

On January 2, 2024 (the “Cubicure Acquisition Date”), we completed the acquisition of privately-held Cubicure GmbH (“Cubicure”) (the “Cubicure Acquisition”). Cubicure is an Austrian company and specializes in direct 3D printing solutions for polymer additive manufacturing that develops, produces, and distributes innovative materials, equipment, and processes for 3D printing solutions. The Cubicure Acquisition is intended to support and scale our strategic innovation roadmap and strengthen the Align Digital Platform. In fiscal year 2021, we acquired a 9.04% equity interest in Cubicure. Subsequently, on the Cubicure Acquisition Date, we acquired the remaining equity of Cubicure. Prior to the acquisition, we also had technology license and joint development agreements with Cubicure.

The fair value of consideration transferred in the acquisition is shown in the table below (in thousands):

Cash paid to Cubicure Stockholders	\$ 80,142
Fair value of pre-existing equity interest ownership	7,968
Settlement of pre-existing relationship - accounts payable	(2,316)
Total purchase consideration paid	<u>\$ 85,794</u>

The Cubicure Acquisition was accounted for as a business combination under ASC Topic 805, Business Combinations (“ASC 805”) that was achieved in stages. As a result of the Cubicure Acquisition, we remeasured our pre-existing equity interest in Cubicure at fair value prior to the Cubicure Acquisition. Based on the fair value of this equity interest, derived from the purchase price, we estimated the fair value of our 9.04% pre-existing investment in Cubicure to be approximately \$8.0 million. The remeasurement resulted in the recognition of a pre-tax gain of \$4.1 million, which was reflected as a component of Other income (expense), net within our Consolidated Statements of Operations.

In 2021, we initiated Joint development (“JDA”) and Technology license agreements (“TLA”) to provide us with access to Cubicure’s technology. The settlement of the JDA and TLA were concluded to be at market terms on the Cubicure Acquisition Date; therefore, no gain or loss was recorded related to the settlement of these contracts. We also had accounts payable from the pre-existing arrangements with Cubicure of \$2.3 million, which were effectively settled and reduced from the purchase consideration of the Cubicure Acquisition.

The allocation of purchase price to assets acquired and liabilities assumed is as follows (in thousands):

Working capital	\$	1,039
Property & equipment		975
Developed technology		47,000
Other non-current asset		1,483
Other liabilities		(12,279)
Goodwill		47,576
Total	\$	<u>85,794</u>

Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and identifiable intangible assets, and represents the value associated with future technology, future customer relationships, and the knowledge and experience of the workforce in place. None of this goodwill is deductible for tax purposes. We allocated all goodwill to our Clear Aligner reporting unit.

As part of the Cubicure Acquisition we acquired a developed technology intangible asset. The acquired developed technology had an estimated fair value of \$47.0 million as of the Cubicure Acquisition Date and will be amortized over a useful life of thirteen years.

The fair value of developed technology was estimated under the Multi-Period Excess Earnings Method and the fair value estimates for developed technology include significant assumptions in the prospective financial information which include, but are not limited to, the projected future cash flows associated with the technology, asset's life cycle and the present value factor.

Acquisition related costs are recognized separately from the business combination and are expensed as incurred. Acquisition related costs were not material.

Our consolidated financial statements include the operating results of Cubicure from the Cubicure Acquisition Date. Separate post-acquisition operating results and pro forma results of operations for this acquisition have not been presented as the effect is not material to our consolidated financial results.

## Note 6. Goodwill and Intangible Assets

### Goodwill

The change in the carrying value of goodwill for the year ended December 31, 2024 and 2023, categorized by reportable segment, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
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
Additions from acquisition	47,576	—	47,576
Foreign currency translation adjustments	(6,017)	(18,459)	(24,476)
Balance as of December 31, 2024	\$ 152,645	\$ 289,985	\$ 442,630

We completed our annual goodwill impairment assessment in 2024 and 2023 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, 2024	Accumulated Amortization	Accumulated Impairment Loss	Net Carrying Value as of December 31, 2024
Existing technology	11	\$ 146,651	\$ (52,238)	\$ —	\$ 94,413
Customer relationships	10	21,500	(10,079)	—	11,421
Trademarks and tradenames	10	16,600	(9,255)	(4,122)	3,223
Patents	12	480	(280)	—	200
		<u>\$ 185,231</u>	<u>\$ (71,852)</u>	<u>\$ (4,122)</u>	<u>109,257</u>
Foreign currency translation adjustments					(5,769)
Total intangible assets, net					<u>\$ 103,488</u>

	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
		<u>\$ 156,662</u>	<u>\$ (67,081)</u>	<u>\$ (8,450)</u>	<u>81,131</u>
Foreign currency translation adjustments					987
Total intangible assets, net					<u>\$ 82,118</u>

Of the \$146.7 million recorded as Existing technology intangible assets as of December 31, 2024, \$47.0 million was acquired during the first quarter of 2024 as part of the Cubicure Acquisition. The existing technology acquired in the Cubicure Acquisition had an estimated useful life of 13 years, which had the effect of increasing the weighted average amortization period from approximately 10 years as of December 31, 2023 to approximately 11 years as of December 31, 2024. Refer to Note 5. "Business Combination".

For the year ended December 31, 2024 and 2023, 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 future amortization expense for these acquired finite-lived intangible assets as of December 31, 2024 is as follows (in thousands):

Fiscal Year	Amortization
2025	\$ 18,651
2026	17,969
2027	15,607
2028	14,505
2029	14,505
Thereafter	28,020
Total amortization	<u>\$ 109,257</u>

Amortization expense was \$18.9 million, \$16.4 million and \$16.0 million for the year ended December 31, 2024, 2023 and 2022, respectively.

#### **Note 7. 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, 2024, 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 8. 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 consolidated action has been resolved per the settlement discussed below.

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 then-current members of our Board of Directors along with certain of our executive officers. The allegations in the complaint were similar to those in the derivative suits described above. The matter has been resolved per the settlement discussed below.

In the first quarter of 2024, the parties to these actions entered into a settlement agreement whereby, plaintiffs dismissed the lawsuits and released their claims. In the settlement agreement, Align and the defendants deny any wrongdoing and are not making any monetary payments, other than an award of \$575,000 in attorney’s fees to plaintiffs’ counsel, covered by insurance. On February 4, 2025, the court granted final approval of the settlement and closed the case.

##### *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. 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. Plaintiffs have appealed the district court’s summary judgment ruling to the United States Court of Appeals for the Ninth Circuit. Oral argument is scheduled for April 10, 2025.

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. On February 21, 2024, the court granted Align's motion for summary judgment on the claims related to Section 2 allegations. The court entered judgment for the Section 2 and related state law claims on March 22, 2024. Plaintiffs have appealed the district court's summary judgment ruling to the United States Court of Appeals for the Ninth Circuit. Oral argument is scheduled for April 10, 2025.

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.

In June 2024, Align and the Section 1 plaintiffs reached a settlement in principle that would resolve all remaining claims in the Section 1 lawsuit. The settlement terms included a \$27.5 million cash payment and coupons for class members. We agreed to settle the lawsuit to avoid the distraction and uncertainty of litigation. The plaintiffs have filed a motion requesting the Court approve the settlement. We are unable to predict the timeline or outcome of the motion to approve the settlement. We continue to believe that plaintiffs' Section 1 claims are without merit and remain ready to vigorously defend ourselves against those claims.

For the year ended December 31, 2024 Align accrued a loss of \$27.5 million for the settlement of the Section 1 claims described above.

#### *Straumann Litigation*

On April 11, 2024, we filed a lawsuit in the U.S. District Court for the Western District of Texas against ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc., and Institut Straumann AG. The complaint asserts claims of false advertising, unfair competition, civil conspiracy, and infringement of Align patents related to aligner material, treatment planning, and intraoral scanner technologies. Among other things, the complaint seeks relief enjoining the defendants' infringement of multiple Align multilayer material patents through defendants' manufacture, sale and offer for sale of aligners made with Zendura FLX/ClearQuartz materials. On June 20, 2024, Defendants filed motions to dismiss the Complaint, which are pending. On July 9, 2024, ClearCorrect Operating, LLC, ClearCorrect Holdings, Inc. and Straumann USA LLC filed counterclaims against Align for alleged antitrust violations, false advertising, unfair competition, and breach of contract. Among other things, the counterclaims seek relief enjoining Align's accused business practices, invalidating Align's asserted patents, and money damages. On September 13, 2024, we filed a motion to dismiss defendants' counterclaims. On February 7, 2025, the magistrate judge recommended denial of the motion to dismiss. On February 21, 2025, we filed objections to the recommendation, which are pending before the district court judge. The District Court has scheduled a trial for February 16, 2026. Align believes these claims are without merit and intends to vigorously defend itself. Align is currently unable to predict the outcome of this lawsuit and cannot determine the likelihood of loss nor estimate a range of possible loss.

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 9. Commitments and Contingencies**

### ***Tax Matter***

Beginning in the third quarter of 2023 and continuing through the first quarter of 2024, the Company received cumulative assessments of approximately \$100 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 October 2019 through May 2023. We were required to pay these assessments prior to contesting or litigating the matter in statutory appeal. 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.

In October 2024, the Company and HMRC reached a settlement agreement regarding the unpaid VAT related to certain aligner sales made during the period of October 2019 through mid-October 2023. As part of the settlement, HMRC agreed to vacate the judicial review (before the Administrative Court) originally scheduled for October 9th and October 10th, 2024, refund to the Company all assessments paid for the period of October 2019 through May 2023 and withdraw any potential assessments for the period from June 2023 through mid-October 2023. HMRC has refunded to the Company all assessed amounts, approximately \$100 million.

The Company has remaining exposure in the amount of approximately \$7.0 million for periods up to December 2023. A statutory appeal (before the First-tier Tribunal - "Tax Tribunal") was held on January 27th through January 30th, 2025. We anticipate that the Tax Tribunal will determine whether clear aligners are exempt from VAT as a matter of law and whether the Company has any liability as a matter of principle in the first half of 2025. It is not possible at this stage to accurately evaluate the likelihood of an unfavorable outcome from the Tax Tribunal statutory appeal. The Company has determined that a potential loss related to VAT accounted for in the periods up to December 2023 is not probable.

### ***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 of future payments, if any, 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, 2024, we did not have any material indemnification claims that were probable or reasonably possible.

## **Note 10. 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 shares against the plan reserve will be returned at the same ratio.

As of December 31, 2024, the 2005 Incentive Plan, as amended, has a total reserve of 32,168,895 shares for issuance of which 3,530,580 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, 2024, 2023 and 2022 is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cost of net revenues	\$ 6,995	\$ 7,462	\$ 6,438
Selling, general and administrative	123,979	115,992	103,134
Research and development	42,729	30,572	23,795
Total stock-based compensation	<u>\$ 173,703</u>	<u>\$ 154,026</u>	<u>\$ 133,367</u>

The income tax benefit related to stock-based compensation was \$19.0 million, \$17.1 million and \$14.9 million for the year ended December 31, 2024, 2023 and 2022, 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, 2024 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, 2023	736	\$ 367.63		
Granted	657	307.12		
Vested and released	(256)	370.36		
Forfeited	(118)	340.47		
Unvested as of December 31, 2024	<u>1,019</u>	\$ 331.10	1.4	\$ 212,468

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 2024 by the number of unvested RSUs) that would have been received by the unit holders had all RSUs vested and been released on the last trading day of fiscal year 2024. This amount will fluctuate based on the fair market value of our stock. During 2024, of the 255,643 shares vested and released, 77,212 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 178,431 shares.

The total fair value of RSUs vested as of their respective vesting dates during 2024, 2023 and 2022 was \$78.8 million, \$63.0 million and \$93.7 million, respectively. The weighted average grant date fair value of RSUs granted during 2024, 2023 and 2022 was \$307.12, \$316.16 and \$469.12, respectively. As of December 31, 2024, we expect to recognize \$216.0 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 2.5 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, 2024:

	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, 2023	158	\$ 811.06		
Granted	83	617.79		
Vested and released	(32)	1,102.09		
Forfeited	(16)	809.22		
Unvested as of December 31, 2024	<u>193</u>	\$ 679.14	1.4	\$ 40,272

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 2024 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 2024. This amount will fluctuate based on the fair



market value of our stock. During 2024, of the 32,369 shares vested and released, 13,388 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 18,981 shares.

The total fair value of MSUs vested as of their respective vesting dates during 2024, 2023 and 2022 was \$10.1 million, \$7.8 million and \$64.0 million, respectively. As of December 31, 2024, we expect to recognize \$51.9 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,		
	2024	2023	2022
Expected term (in years)	3.0	3.0	3.0
Expected volatility	52.0 %	59.1 %	53.8 %
Risk-free interest rate	4.3 %	4.3 %	1.7 %
Expected dividends	—	—	—
Weighted average fair value per share at grant date	\$ 617.79	\$ 629.53	\$ 915.22

### ***Restricted Stock Units with Performance Conditions (“PSUs”)***

Our PSUs typically include a service and performance condition. We recognize share-based compensation expense for PSUs if it is probable that the performance condition will be achieved.

The following table summarizes the PSU performance activity for the year ended December 31, 2024:

	Number of Shares Underlying PSUs (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, 2023	\$ 5	\$ 201.63		
Granted	6	206.36		
Vested and released	—	—		
Forfeited	—	—		
Unvested as of December 31, 2024	\$ 11	\$ 204.33	1.2	\$ 2,299

As of December 31, 2024, we expect to recognize \$1.0 million of total unamortized compensation costs, net of estimated forfeitures, related to PSUs over a weighted average period of 1.2 years.

### ***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,		
	2024	2023	2022
Number of shares issued (in thousands)	120	114	86
Weighted average price	\$ 213.11	\$ 234.19	\$ 305.24

As of December 31, 2024, 1,875,920 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,		
	2024	2023	2022
Expected term (in years)	1.3	1.2	1.5
Expected volatility	49.2 %	56.4 %	50.2 %
Risk-free interest rate	4.6 %	4.9 %	1.8 %
Expected dividends	—	—	—
Weighted average fair value at grant date	\$ 94.75	\$ 132.94	\$ 159.44

We recognized stock-based compensation related to our employee stock purchase plan of \$14.0 million, \$20.5 million and \$23.5 million for the year ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, we expect to recognize \$11.5 million of total unamortized compensation costs related to future employee stock purchases over a weighted average period of 0.7 years.

#### Note 11. 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”), which was completed in March 2023. In January 2023, our Board of Directors authorized a new plan to repurchase up to \$1.0 billion of our common stock (“January 2023 Repurchase Program”). The January 2023 Repurchase Program does not have an expiration date.

##### *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, 2024 and 2023:

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
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	Q1 2024	1,086,334	\$ 230.13

##### *Open Market Common Stock Repurchases*

Agreement Date	Repurchase Program	Amount Paid (in millions)	Completion Date	Total Shares Received	Average Price per Share
Q4 2023	January 2023	\$ 100.0	Q4 2023	465,518	\$ 214.81
Q2 2024	January 2023	\$ 150.0	Q2 2024	598,302	\$ 250.73
Q4 2024	January 2023	\$ 202.9	N/A <sup>1</sup>	909,967	\$ 222.94

<sup>1</sup> In January 2025, we completed the open market repurchase program initiated in Q4 2024. In total we repurchased approximately 1.2 million shares of our common stock at an average price of \$221.50 per share, including commissions and fees, for an aggregate purchase price of approximately \$275.0 million.

As of December 31, 2024 we had \$297.1 million available for repurchases under the January 2023 Repurchase Program. In January 2025 we repurchased \$72.1 million of our common stock initiated in the Q4 2024 open market repurchase program.

## Note 12. Employee Benefit Plans

We have a defined contribution retirement plan as defined in Section 401(k) of the Internal Revenue Code for our U.S. employees which covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. We match 50% of our employee's salary deferral contributions up to 6% of the employee's eligible compensation. We contributed approximately \$10.0 million, \$9.5 million and \$10.0 million to the 401(k) plan during the year ended December 31, 2024, 2023 and 2022, respectively. We also have defined contribution retirement plans outside of the U.S. to which we contributed \$57.4 million, \$55.1 million and \$54.5 million during the year ended December 31, 2024, 2023 and 2022, respectively.

## Note 13. Income Taxes

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

	Year Ended December 31,		
	2024	2023	2022
Domestic	\$ 334,485	\$ 315,643	\$ 268,097
Foreign	274,474	325,561	330,960
Net income before provision for income taxes	<u>\$ 608,959</u>	<u>\$ 641,204</u>	<u>\$ 599,057</u>

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

	Year Ended December 31,		
	2024	2023	2022
Federal			
Current	\$ 95,027	\$ 134,332	\$ 188,050
Deferred	1,578	(16,805)	(55,579)
	<u>96,605</u>	<u>117,527</u>	<u>132,471</u>
State			
Current	13,702	28,535	34,621
Deferred	3,384	(3,157)	(12,265)
	<u>17,086</u>	<u>25,378</u>	<u>22,356</u>
Foreign			
Current	56,653	51,306	56,537
Deferred	17,253	1,940	26,120
	<u>73,906</u>	<u>53,246</u>	<u>82,657</u>
Provision for (benefit from) income taxes	<u>\$ 187,597</u>	<u>\$ 196,151</u>	<u>\$ 237,484</u>

The differences between income taxes using the federal statutory income tax rate for the year ended December 31, 2024, 2023 and 2022 and our effective tax rates are as follows:

	Year Ended December 31,		
	2024	2023	2022
U.S. federal statutory income tax rate	21.0 %	21.0 %	21.0 %
State income taxes, net of federal tax benefit	2.2	2.9	3.7
U.S. tax on foreign earnings	5.4	3.7	5.6
Impact of differences in foreign tax rates	(2.0)	1.4	3.3
Stock-based compensation	3.4	3.0	2.1
Settlement on audits	—	0.1	1.9
Change in valuation allowance	0.9	(1.3)	1.7
Other items not individually material	(0.1)	(0.2)	0.3
Effective tax rate	<u>30.8 %</u>	<u>30.6 %</u>	<u>39.6 %</u>

Certain countries in which we operate, including Switzerland, have adopted legislation to implement the OECD/G20 Framework's Pillar Two 15% global minimum tax ("Pillar Two"). The adoption of legislation to implement Pillar Two did not have a material effect on our provision for income taxes for the year ended December 31, 2024.

We continue to evaluate opportunities to repatriate our foreign earnings if or when needed. We do not expect to incur significant additional costs upon repatriation of these foreign earnings.

As of December 31, 2024 and 2023, the significant components of our deferred tax assets and liabilities are (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss and capital loss carryforwards	\$ 2,741	\$ 1,389
Reserves and accruals	67,221	62,891
Stock-based compensation	29,255	25,054
Deferred revenue	146,509	142,082
Capitalized research & development	32,027	41,505
Amortizable tax basis in intangibles	1,301,338	1,325,236
Other	12,282	13,228
Deferred tax assets before valuation allowance	1,591,373	1,611,385
Valuation allowance	(19,390)	(14,991)
Total deferred tax assets	\$ 1,571,983	\$ 1,596,394
Deferred tax liabilities:		
Depreciation and amortization	\$ 16,485	\$ 7,814
Acquisition-related intangibles	28,868	25,097
Other	4,511	3,570
Total deferred tax liabilities	49,864	36,481
Net deferred tax assets	\$ 1,522,119	\$ 1,559,913

As of December 31, 2024, 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, 2024 was \$19.4 million. During the year ended December 31, 2024, the valuation allowance increased by \$4.4 million primarily due to the change in deferred tax assets associated with certain interest expense, net operating loss carryovers, and unrealized translation losses from our German subsidiaries. We may be required to adjust the valuation allowance for deferred tax assets if we determine, based on available evidence at the time of the determination, that it is more likely than not that some portion or all of the deferred tax assets will not be realized. Changes to the valuation allowance could have a material adverse effect on our results of operations.

As of December 31, 2024, we have foreign net operating loss carryforwards of approximately \$8.7 million, attributed mainly to losses in Austria, Russia, and Germany. The losses in Austria and Germany can be carried forward indefinitely. The operating loss carryforwards in Russia, if not utilized, will expire beginning 2033.

The changes in the balance of gross unrecognized tax benefits, which exclude interest and penalties, for the year ended December 31, 2024, 2023 and 2022, are as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Gross unrecognized tax benefits at January 1,	\$ 149,172	\$ 141,560	\$ 63,295
Increases related to tax positions taken during the current year	12,264	8,616	84,249
Increases related to tax positions taken during a prior year	2,031	5,647	15,411
Decreases related to tax positions taken during a prior year	(3,924)	(533)	(2,647)
Decreases related to expiration of statute of limitations	(14,009)	(3,654)	(4,582)
Decreases related to settlement with tax authorities	—	(2,464)	(14,166)
Gross unrecognized tax benefits at December 31,	\$ 145,534	\$ 149,172	\$ 141,560

The total amount of gross unrecognized tax benefits as of December 31, 2024 was \$145.5 million, of which \$139.0 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. We are under IRS audit for U.S. federal tax returns from 2018 to 2020. For U.S. state tax returns, we are no longer subject to tax examinations for years before 2019. 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, 2024, 2023 and 2022 as well as accrued as of December 31, 2024 and 2023 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 14. 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,		
	2024	2023	2022
Numerator:			
Net income	\$ 421,362	\$ 445,053	\$ 361,573
Denominator:			
Weighted average common shares outstanding, basic	74,877	76,426	78,190
Dilutive effect of potential common stock	116	142	230
Total shares, diluted	74,993	76,568	78,420
Net income per share, basic	\$ 5.63	\$ 5.82	\$ 4.62
Net income per share, diluted	\$ 5.62	\$ 5.81	\$ 4.61
Anti-dilutive potential common shares <sup>1</sup>	685	293	320

<sup>1</sup> Represents approximately 685 thousand RSU for the year ended December 31, 2024, approximately 263 thousand RSU and 30 thousand ESPP weighted-average outstanding common stock equivalent shares for the year ended December 31, 2023 and approximately 320 thousand RSU for the year ended December 31, 2022 that are excluded from the calculation of diluted net income per share as the effect would have been anti-dilutive.

**Note 15. Supplemental Cash Flow Information**

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

	Year Ended December 31,		
	2024	2023	2022
Taxes paid	\$ 177,082	\$ 294,569	\$ 231,884
Non-cash investing and financing activities:			
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	\$ 18,974	\$ 32,280	\$ 35,767
Final settlement of prior year stock repurchase forward contract	\$ 50,000	\$ 40,000	\$ —
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	\$ 39,526	\$ 33,714	\$ 31,015
Right-of-use assets obtained in exchange for lease obligations:			
Operating leases	\$ 32,671	\$ 27,901	\$ 34,144

**Note 16. 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 (“CODM”), our Chief Executive Officer, for decision making and performance assessment as the basis for determining our reportable segments. We group our operations into two reportable segments: Clear Aligner segment and Imaging Systems and CAD/CAM services (“Systems and Services”) segment, which are based on our predominant product lines.

Our CODM uses gross profit and income from operations to assess each reportable segments performance, by reviewing each measure against internal forecasts and historical performance. Our CODM may also benchmark each segments performance against our competitors and external expectations.

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

	Year Ended December 31,		
	2024	2023	2022
Net revenues			
Clear Aligner	\$ 3,230,122	\$ 3,199,329	\$ 3,072,585
Systems and Services	768,890	662,931	662,050
Total net revenues	<u>\$ 3,999,012</u>	<u>\$ 3,862,260</u>	<u>\$ 3,734,635</u>
Cost of net revenues <sup>1</sup>			
Clear Aligner	\$ 952,136	\$ 911,291	\$ 844,415
Systems and Services	247,717	244,106	256,445
Total cost of goods sold	<u>\$ 1,199,853</u>	<u>\$ 1,155,397</u>	<u>\$ 1,100,860</u>
Gross Profit			
Clear Aligner	\$ 2,277,986	\$ 2,288,038	\$ 2,228,170
Systems and Services	521,173	418,825	405,605
Total gross profit	<u>\$ 2,799,159</u>	<u>\$ 2,706,863</u>	<u>\$ 2,633,775</u>
Other Segment expenses			
Clear Aligner	\$ 1,135,782	\$ 1,105,781	\$ 1,093,750
Systems and Services	251,951	227,470	225,840
Unallocated corporate expenses	803,798	730,274	671,590
Total operating expenses	<u>\$ 2,191,531</u>	<u>\$ 2,063,525</u>	<u>\$ 1,991,180</u>
Segment income from operations			
Clear Aligner	\$ 1,142,204	\$ 1,182,257	\$ 1,134,420
Systems and Services	269,222	191,355	179,765
Total segment income from operations	<u>\$ 1,411,426</u>	<u>\$ 1,373,612</u>	<u>\$ 1,314,185</u>

<sup>1</sup> Management has identified cost of net revenues as a significant expense for our Clear Aligner and Systems and Services reportable segments.

Other segment expenses typically include employee related costs, marketing and advertising costs, and depreciation and amortization expense incurred by various functions including selling, marketing, general and administrative and research and development. Our CODM does not regularly receive these operating expenses at the reportable segment level.

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.

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,		
	2024	2023	2022
Segment income from operations	\$ 1,411,426	\$ 1,373,612	\$ 1,314,185
Unallocated corporate expenses	(803,798)	(730,274)	(671,590)
Total income from operations	607,628	643,338	642,595
Interest income	20,218	17,258	5,367
Other income (expense), net	(18,887)	(19,392)	(48,905)
Net income before provision for income taxes	<u>\$ 608,959</u>	<u>\$ 641,204</u>	<u>\$ 599,057</u>

The following table includes certain non-cash expenses for each reportable segment (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Stock-based compensation			
Clear Aligner	\$ 22,888	\$ 13,963	\$ 14,816
Systems and Services	1,595	1,293	994
Unallocated corporate expenses	149,220	138,770	117,557
Total stock-based compensation	<u>\$ 173,703</u>	<u>\$ 154,026</u>	<u>\$ 133,367</u>
Depreciation and amortization			
Clear Aligner	\$ 67,450	\$ 64,781	\$ 57,888
Systems and Services	30,998	31,518	28,300
Unallocated corporate expenses	46,586	46,102	39,605
Total depreciation and amortization	<u>\$ 145,034</u>	<u>\$ 142,401</u>	<u>\$ 125,793</u>

Our CODM 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,		
	2024	2023	2022
Net revenues <sup>1</sup> :			
U.S.	\$ 1,695,696	\$ 1,665,925	\$ 1,660,045
Switzerland	983,629	1,168,320	1,216,094
Other International	1,319,687	1,028,015	858,496
Total net revenues	<u>\$ 3,999,012</u>	<u>\$ 3,862,260</u>	<u>\$ 3,734,635</u>

<sup>1</sup> 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,	
	2024	2023
Long-lived assets <sup>1</sup> :		
Switzerland	\$ 571,628	\$ 575,432
U.S.	207,689	210,275
Other International	605,193	623,155
Total long-lived assets	<u>\$ 1,384,510</u>	<u>\$ 1,408,862</u>

<sup>1</sup> Long-lived assets are attributed to countries based on the location of our entity that owns or leases the assets.

## **Note 17. Restructuring and Other Charges**

### ***2023 Restructuring***

During the fourth quarter of 2023, 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. Our fourth quarter 2023 restructuring activities were substantially complete by the third quarter of 2024.

### ***2024 Restructuring***

During the fourth quarter of 2024, we initiated a restructuring plan to increase efficiencies across the organization which is expected to be completed in 2025. We incurred approximately \$37.0 million in restructuring expenses, of which \$3.8 million



was recorded in Cost of net revenues and \$33.2 million was recorded in Restructuring and other charges. These restructuring activities were primarily related to employee severance and other one-time post-employment benefits.

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

	<b>Restructuring and other charges</b>
Balance as of December 31, 2022 <sup>1</sup>	\$ 3,916
Restructuring charges	13,989
Cash payments and adjustments	(12,606)
Balance as of December 31, 2023 <sup>1</sup>	5,299
Restructuring charges <sup>2</sup>	36,393
Cash payments and adjustments	(28,691)
Balance as of December 31, 2024 <sup>1</sup>	<u>\$ 13,001</u>

<sup>1</sup> Included in “Accrued liabilities” within our Consolidated Balance Sheets.

<sup>2</sup> Includes approximately \$0.6 million of restructuring expense decreases related to the 2023 restructuring.

## **Note 18. Subsequent Events**

On February 25, 2025, we announced a plan to repurchase \$225.0 million of our common stock through open market repurchases. We expect these repurchases to be completed by the beginning of May 2025. The number of shares to be repurchased and the average price per share are not determinable as of the filing of this Annual Report on Form 10-K. Upon completion of these open market repurchases the Company will have exhausted all funds available under the January 2023 Repurchase Program.

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

Not applicable.

## **Item 9A. Controls and Procedures.**

### ***Evaluation of Disclosure Controls and Procedures.***

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, has 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, 2024 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 SEC’s rules and forms.

### ***Management’s Annual Report on Internal Control over Financial Reporting.***

See “Management’s Annual Report on Internal Control over Financial Reporting” in Item 8 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 (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2024 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, 2024, 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 Item 408 of Regulation S-K).

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

Not applicable.

### **PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we intend to file our definitive Proxy Statement for our 2025 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 section entitled “Director Nominees” contained in the Proxy Statement.

The information required by Item 401 of Regulation S-K concerning our executive officers is set forth in Part I, Item 1, “Business” contained in this Annual Report on Form 10-K under the section entitled “Information about our Executive Officers.”

If applicable, the information required by Item 405 of Regulation S-K concerning delinquent reports under Section 16(a) of the Exchange Act will be 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 section entitled “Corporate Governance” contained in the Proxy Statement.

##### ***Insider Trading Arrangements and Policies***

We have adopted an Insider Trading Policy governing the purchase, sale and other dispositions of our securities by our directors, officers, employees, consultants, contractors and our agents that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations and Nasdaq listing standards. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K for the fiscal year ended December 31, 2024. In addition, it is our policy that any trades by us will comply with applicable law, including laws with respect to insider trading.

##### ***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 our Global Code of Conduct by posting such information on our website, at the address and location specified above, rather than by filing a Current Report on Form 8-K.

#### **Item 11. Executive Compensation.**

The information required by Item 402 of Regulation S-K is incorporated by reference to the sections entitled “Executive Compensation—Compensation Discussion and Analysis,” “Compensation Tables” and “Director Compensation” contained in the Proxy Statement.

The information required by Items 407(e)(4) and (e)(5) of Regulation S-K is incorporated by reference to the sections entitled “Corporate Governance—Committee Responsibilities and Oversight—Compensation and Human Capital Committee—Compensation Committee Interlocks and Insider Participation” and “Compensation and Human Capital Committee Report,” respectively, contained in the Proxy Statement.

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

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

**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 sections entitled “Certain Relationships and Related Party Transactions” and “Corporate Governance—Board Structure and Independence,” respectively, contained in the Proxy Statement.

**Item 14. Principal Accountant Fees and Services.**

The information required by Item 9(e) of Schedule 14A is incorporated by reference to the section entitled “Ratification of Appointment of Independent Registered Public Accounting Firm” contained in the Proxy Statement.

## 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	<a href="#">57</a>
Consolidated Statements of Operations for the year ended December 31, 2024, 2023 and 2022	<a href="#">59</a>
Consolidated Statements of Comprehensive Income for the year ended December 31, 2024, 2023 and 2022	<a href="#">60</a>
Consolidated Balance Sheets as of December 31, 2024 and 2023	<a href="#">61</a>
Consolidated Statements of Stockholders' Equity for the year ended December 31, 2024, 2023 and 2022	<a href="#">62</a>
Consolidated Statements of Cash Flows for the year ended December 31, 2024, 2023 and 2022	<a href="#">63</a>
Notes to Consolidated Financial Statements	<a href="#">64</a>

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, 2024, 2023 and 2022

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)			
<b>Allowance for doubtful accounts:</b>				
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
Year Ended December 31, 2024	\$ 14,893	\$ 8,282	\$ (4,044)	\$ 19,131
<b>Valuation allowance for deferred tax assets:</b>				
Year Ended December 31, 2022	\$ 12,938	\$ 10,348	\$ —	\$ 23,286
Year Ended December 31, 2023	\$ 23,286	\$ (8,295)	\$ —	\$ 14,991
Year Ended December 31, 2024	\$ 14,991	\$ 4,399	\$ —	\$ 19,390

(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
<a href="#">3.1</a>	<a href="#">Amended and Restated Certificate of Incorporation of Align Technology, Inc</a>	S-1/A (File No. 333-49932)	12/28/2000	3.1	
<a href="#">3.1A</a>	<a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Align Technology, Inc.</a>	8-K	5/20/2016	3.01	
<a href="#">3.1B</a>	<a href="#">Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Align Technology, Inc.</a>	10-Q	8/4/2023	3.1B	
<a href="#">3.2</a>	<a href="#">Amended and Restated Bylaws of Align Technology, Inc.</a>	8-K	1/17/2024	3.1	
<a href="#">4.1</a>	<a href="#">Form of Specimen Common Stock Certificate</a>	S-1/A (File No. 333-49932)	1/17/2001	4.1	
<a href="#">4.2</a>	<a href="#">Description of the Registered Securities of Align Technology, Inc.</a>				*
<a href="#">10.1A†</a>	<a href="#">Align Technology, Inc. 2010 Employee Stock Purchase Plan (as amended and restated as of May 19, 2021)</a>	8-K	5/20/2021	10.1	
<a href="#">10.2†</a>	<a href="#">Align Technology, Inc. 2005 Incentive Plan (as amended and restated May 17, 2023)</a>	8-K	5/18/2023	10.1	
<a href="#">10.3†</a>	<a href="#">Form of RSU Agreement under 2005 Incentive Plan (Officer Form for officers appointed after September 2016)</a>	10-K	2/28/2020	10.3	
<a href="#">10.3A†</a>	<a href="#">Form of RSU Agreement under 2005 Incentive Plan (Officer Form for officers appointed prior to September 2016)</a>	10-K	2/28/2020	10.3A	
<a href="#">10.4†#</a>	<a href="#">Form of RSU Agreement (CEO)</a>				*
<a href="#">10.5†</a>	<a href="#">Form of RSU Agreement under Registrant's 2005 Incentive Plan (Non-employee Director Form)</a>	10-K	2/28/2020	10.5	
<a href="#">10.6†</a>	<a href="#">Align 2019 Global RSU Agreement</a>	10-K	2/28/2019	10.6	
<a href="#">10.7†#</a>	<a href="#">Form of Restricted Stock Unit Agreement under 2005 Incentive Plan (CEO Form)</a>				*
<a href="#">10.8†</a>	<a href="#">Form of Restricted Stock Unit Agreement under Registrant's 2005 Incentive Plan (Executive Officer Form for officers appointed after September 2016)</a>	10-Q	5/5/2023	10.2	
<a href="#">10.9†</a>	<a href="#">Form of Restricted Stock Unit Agreement under Registrant's 2005 Incentive Plan (Executive Officer Form for officers appointed prior to September 2016)</a>	10-Q	5/5/2023	10.3	
<a href="#">10.10†</a>	<a href="#">Form of Option Award Agreement under Registrant's 2005 Incentive Plan</a>	10-Q	8/4/2005	10.4	
<a href="#">10.11†</a>	<a href="#">Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2019, 2020 and 2022 to officers appointed after September 2016)</a>	10-K	2/28/2020	10.8	
<a href="#">10.11A†</a>	<a href="#">Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2019, 2020 and 2022 to officers appointed prior to September 2016)</a>	10-K	2/28/2020	10.8A	
<a href="#">10.12†</a>	<a href="#">Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2021 to officers appointed after September 2016)</a>	10-K	2/26/2021	10.9	
<a href="#">10.12A†</a>	<a href="#">Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2021 to officers appointed prior to September 2016)</a>	10-K	2/26/2021	10.9A	
<a href="#">10.13†</a>	<a href="#">Form of Market Stock Unit Agreement for CEO (Focal grants)</a>	10-K	2/28/2020	10.9	
<a href="#">10.14†</a>	<a href="#">Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (CEO Form)</a>	10-Q	5/5/2023	10.4	
<a href="#">10.15†</a>	<a href="#">Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Executive Officer Form for officers appointed after September 2016)</a>	10-Q	5/5/2023	10.5	

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
<a href="#"><u>10.16†</u></a>	<a href="#"><u>Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Executive Officer Form for officers appointed prior to September 2016)</u></a>	10-Q	5/5/2023	10.6	
<a href="#"><u>10.17†</u></a>	<a href="#"><u>Form of Employment Agreement entered into by and between Align Technology, Inc. and each executive officer (non-CEO Form) (for executive officers appointed prior to September 2016)</u></a>	10-Q	5/8/2008	10.3	
<a href="#"><u>10.18†</u></a>	<a href="#"><u>Form of Employment Agreement entered into by and between Align Technology, Inc. and each executive officer (non-CEO Form) (for executive officers appointed after September 2016)</u></a>	10-K	2/28/2017	10.8	
<a href="#"><u>10.19†</u></a>	<a href="#"><u>Amended and Restated Chief Executive Officer Employment Agreement, dated as of April 16, 2025, between Align Technology, Inc. and Joseph Hogan</u></a>	10-Q	5/1/2015	10.30	
<a href="#"><u>10.20†</u></a>	<a href="#"><u>Employment Agreement, dated as of April 16, 2025, between Align Technology, Inc. and John F. Morici</u></a>	10-Q	11/8/2016	10.2	
<a href="#"><u>10.21†</u></a>	<a href="#"><u>Form of Indemnification Agreement by and between Align Technology, Inc. and its Board of Directors and its executive officers</u></a>	S-1/A (File No. 333-49932)	1/17/2001	10.15	
<a href="#"><u>10.22</u></a>	<a href="#"><u>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</u></a>	10-Q	10/30/2020	10.1	
<a href="#"><u>10.23</u></a>	<a href="#"><u>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</u></a>	10-K	2/27/2023	10.18	
<a href="#"><u>10.24</u></a>	<a href="#"><u>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</u></a>	10-K	2/27/2023	10.19	
<a href="#"><u>10.25</u></a>	<a href="#"><u>Fixed Dollar Accelerated Share Repurchase Transaction between Citibank, N.A and Align Technology, Inc. dated October 26, 2023</u></a>	10-K	2/28/2024	10.26	
<a href="#"><u>10.26</u></a>	<a href="#"><u>Subscription Agreement, dated as of April 24, 2023 between Align Technology, Inc. and Heartland Dental Holding Corporation</u></a>	10-Q	8/4/2023	10.1	
<a href="#"><u>10.27</u></a>	<a href="#"><u>Stockholders' Agreement, dated as of April 24, 2023 by and among Heartland Dental Holding Corporation, Heartland Dental Topco, LLC, KKR Core Holding Company LLC, KKR Partners IV L.P., any Sponsor Group Permitted Transferee as defined in the Agreement and Align Technology, Inc.</u></a>	10-Q	8/4/2023	10.2	
<a href="#"><u>10.28</u></a>	<a href="#"><u>Side Letter, dated as of April 24, 2023 by and among Heartland Dental Holding Corporation, Heartland Dental Topco, LLC, KKR Core Holding Company LLC, KKR Partners IV L.P., any Sponsor Group Permitted Transferee as defined in the Stockholders' Agreement and Align Technology, Inc.</u></a>	10-Q	8/4/2023	10.3	
<a href="#"><u>10.29</u></a>	<a href="#"><u>Share Purchase Agreement, dated September 1, 2023, between Align Holdings GMBH, Align Technology Switzerland GMBH and the Sellers provided therein</u></a>	10-Q	11/3/2023	10.1	
<a href="#"><u>10.30**</u></a>	<a href="#"><u>Subscription Agreement, dated as of April 22, 2024, between Align Technology, Inc. and Heartland Dental Holding Corporation</u></a>	10-Q	8/2/2024	10.1	
<a href="#"><u>19.1</u></a>	<a href="#"><u>Align Technology, Inc. Insider Trading Policy</u></a>				*
<a href="#"><u>21.1</u></a>	<a href="#"><u>Subsidiaries of Align Technology, Inc.</u></a>				*
<a href="#"><u>23.1</u></a>	<a href="#"><u>Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm</u></a>				*
<a href="#"><u>31.1</u></a>	<a href="#"><u>Certifications of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003</u></a>				*
<a href="#"><u>31.2</u></a>	<a href="#"><u>Certifications of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2003</u></a>				*

Exhibit Number	Description	Form	Date	Exhibit Number Incorporated by Reference herein	Filed herewith
<a href="#">32.1</a> ♦	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003</a>				*
<a href="#">97.1</a>	<a href="#">Align Technology, Inc. Clawback Policy</a>	10-K	2/28/2024	97.1	
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 because the omitted information is not material and (i) would likely cause competitive harm to the registrant if publicly disclosed or (ii) is information that the registrant treats as private or confidential.

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

♦ Furnished herewith

# This corrected version of the exhibit supersedes the prior version previously filed with the SEC.

#### Item 16. Form 10-K Summary.

None.

## 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, 2025**

## POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Joseph M. Hogan or John F. Morici, jointly and severally, his or her attorney-in-fact, each with the full power of substitution, for such person 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JOSEPH M. HOGAN</u> <b>Joseph M. Hogan</b>	President, Chief Executive Officer and Director ( <i>Principal Executive Officer</i> )	February 28, 2025
<u>/s/ JOHN F. MORICI</u> <b>John F. Morici</b>	Chief Financial Officer and Executive Vice President, Global Finance ( <i>Principal Financial Officer and Principal Accounting Officer</i> )	February 28, 2025
<u>/s/ KEVIN T. CONROY</u> <b>Kevin T. Conroy</b>	Director	February 28, 2025
<u>/s/ KEVIN J. DALLAS</u> <b>Kevin J. Dallas</b>	Director	February 28, 2025
<u>/s/ JOSEPH LACOB</u> <b>Joseph Lacob</b>	Director	February 28, 2025
<u>/s/ C. RAYMOND LARKIN, JR.</u> <b>C. Raymond Larkin, Jr.</b>	Chairman of the Board	February 28, 2025
<u>/s/ GEORGE J. MORROW</u> <b>George J. Morrow</b>	Director	February 28, 2025
<u>/s/ ANNE M. MYONG</u> <b>Anne M. Myong</b>	Director	February 28, 2025
<u>/s/ MOJDEH POUL</u> <b>Mojdeh Poul</b>	Director	February 28, 2025
<u>/s/ ANDREA L. SAIA</u> <b>Andrea L. Saia</b>	Director	February 28, 2025
<u>/s/ SUSAN E. SIEGEL</u> <b>Susan E. Siegel</b>	Director	February 28, 2025