UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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	FORM 10-K		
(Mark One)			
■ ANNUAL REPORT PURSUANT TO	SECTION 13 OR 15(d) OF THE SI	ECURITIES EXCHANGE AC	CT OF 1934
	For the fiscal year ended December 31, 2 OR	021	
☐ TRANSITION REPORT PURSUANT		HE SECURITIES EXCHANG	E ACT OF 1934
	For the transition period from to Commission file number: 000-32259		
	ALIGN TECHNOLOGY, I (Exact name of registrant as specified in its cha		
Delaware (State or other jurisdiction of incorporation or organization)		94-3267295 (I.R.S. Employer Identification Number)	
	410 North Scottsdale Road, Suite 1300 Tempe, Arizona 85281 (Address of principal executive offices)		
	(602) 742-2000 (Registrant's telephone number, including area	a code)	
Title of each class	Securities registered pursuant to Section 12(b) of Trading Symbol	the Act: Name of each exchange on whice	·h registered
Common Stock, \$0.0001 par value	ALGN	The NASDAQ Stock Mark (NASDAQ Global Mar	et LLC
Sec	curities registered pursuant to Section 12(g) of the	e Act: None	
Indicate by check mark if the registrant is a well-known seaso	oned 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 th	e Exchange Act. Yes □ No ⊠	
Indicate by check mark whether the registrant (1) has filed al for such shorter period that the registrant was required to file such			
Indicate by check mark whether the registrant has submitted chapter) during the preceding 12 months (or for such shorter period			egulation S-T (§232.405 of this
Indicate by check mark whether the registrant is a large acceleration of "large accelerated filer," "accelerated filer," "smaller			
Large accelerated filer	\boxtimes	Accelerated filer	
Non-accelerated filer		Smaller reporting company Emerging growth company	
If an emerging growth company, indicate by check mark it standards provided pursuant to Section $7(a)(2)(B)$ of the Securit	f the registrant has elected not to use the extended trailes Act. \square		\square or revised financial accounting
Indicate by check mark whether the Registrant has filed a respection 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by t			ol over financial reporting under
Indicate by check mark whether the registrant is a shell comp	any (as defined in Rule 12b-2 of the Exchange Act).	Yes □ No ⊠	
The aggregate market value of the registrant's common stock the registrant's common stock on the NASDAQ Global Market on necessarily a conclusive determination for other purposes.			
On February 21, 2022, 78,795,494 shares of the registrant's c	ommon stock were outstanding.		
DOCUMENTS INCORPORATED BY REFERENCE			
Portions of the registrant's definitive Proxy Statement relating year end of December 31, 2021 are incorporated by reference into 1	9	iled pursuant to Regulation 14A within 120	days after the registrant's fiscal

ALIGN TECHNOLOGY, INC.

FORM 10-K

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Invisalign, Align, the Invisalign logo, ClinCheck, Made to Move, Invisalign Assist, Invisalign Teen, Invisalign Go, Vivera, SmartForce, SmartTrack, SmartStage, SmileView, iTero, iTero Element, Orthocad, iCast, iRecord and exocad, 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. These statements include, among other things, our expectations and intentions regarding our strategic objectives and the means to achieve them, our estimates regarding the size and opportunities of the markets we are targeting along with our expectations for growth in those markets, our beliefs regarding the impact of technological innovation in general, and in our solutions and products in particular, on target markets and patient care, our beliefs regarding digital dentistry and its potential to impact our business, our intentions regarding expanding our business, including its impact on our operational flexibility and responsiveness to customer demand, our beliefs regarding the potential for clinical solutions and their utilization to increase sales of our Invisalign system as well as the complementary products and solutions themselves, our beliefs regarding doctor training and its impact on Invisalign system utilization, our beliefs regarding the importance of our manufacturing operations on our success, our beliefs regarding the need for and benefits of our technological development on Invisalign treatment, the areas of development in which we focus our efforts, and the advantages of our intellectual property portfolio, our beliefs regarding our business strategy and growth drivers, our expectations regarding product mix and product adoption, our expectations regarding the utilization rates for our products, including the impact of marketing on those rates and causes for periodic fluctuations of the rates, our expectations regarding the existence and impact of seasonality and the COVID-19 disruptions to seasonality, our expectations regarding the sales growth of our intraoral scanner sales in international markets, our expectations regarding the productivity impact additional sales representatives will have on our sales and the impact of specialization of those representatives in sales channels, our expectations regarding the continued expansion of our international markets and their growth, our expectation regarding customer and consumer purchasing behavior, including expectations related to the consumer demand environment in China especially for U.S. based products and services, our expectations regarding competition and our ability to compete in our target markets, our beliefs concerning our compliance with applicable laws and regulations, our beliefs regarding our culture and commitment and its impact on our financial and operational performance and its importance to our future success, our expectations for future investments in and benefits from consumer demand sales and marketing activities, our expectations regarding the implications of the COVID-19 pandemic and the health, safety and economic impact from it, on the global economy, the businesses of our customers, and us, including our preparedness to react to changing circumstances and overall on our revenues, results of operations and financial condition, our expectations for our expenses and capital obligations and expenditures in particular, the actions we will take to control spending and for investments, our intentions regarding the investment of our international earnings from operations, our belief regarding the sufficiency of our cash balances and borrowing capacity, our judgments regarding the estimates used in our revenue recognition, and assessment of goodwill and intangible assets, our expectations regarding our tax positions and the assumptions we make related to our tax obligations, our expectations regarding potential additional litigation with SDC Financial LLC and certain affiliates, the level of our operating expenses and gross margin and other factors beyond our control, as well as other statements regarding our future operations, financial condition and prospects and business strategies and any other statements that address events or developments that we intend or believe will or may occur in the future. Terminology such as "believe," "anticipate," "should," "could," "intend," "will," "plan," "expect," "estimate," "project," "target," "may," "possible," "potential," "forecast" and "positioned" and similar references to future periods are intended to identify forward-looking statements, although not all forward-looking statements are accompanied by such words. These or any 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", "Our", "Align") is a global medical device company primarily engaged in the design, manufacture and marketing of Invisalign® clear aligners, iTero® intraoral scanners and services for dentistry, and exocad® computer-aided design and computer-aided manufacturing ("CAD/CAM") software for dental laboratories and dental practitioners. We also market and sell consumer products that are complementary to our doctor-prescribed principal products under the Invisalign and other brands, including retainers, aligner cases (clamshells), teeth whitening products and cleaning solutions (crystals, foam and other material) (collectively "Consumer Products"). Our primary goals are to establish clear aligners as the principal solution for the treatment of malocclusions, or the misalignment of teeth, and our Invisalign system as the treatment solution of choice by orthodontists, general dental practitioners and patients globally, our intraoral scanners as the

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

Align's corporate headquarters are located at 410 North Scottsdale Road, Suite 1300, Tempe, Arizona 85281. Our telephone number is 602-742-2000. Our internet address is www.aligntech.com. Our Americas regional headquarters is located in Raleigh, North Carolina, U.S.A.; our European, Middle East and Africa ("EMEA") regional headquarters is located in Rotkreuz, Switzerland; and our Asia Pacific ("APAC") regional headquarters is located in Singapore.

We have two operating segments: (1) Clear Aligner and (2) Imaging Systems and CAD/CAM Services ("Systems and Services"). For the year ended December 31, 2021, Clear Aligner net revenues represented approximately 82% of worldwide net revenues, while Systems and Services net revenues represented the remaining 18%. We sell the majority of our products directly through a dedicated and specialized sales force to our customers: orthodontists, general practitioner dentists ("GPs"), restorative and aesthetic dentists, including prosthodontists, periodontists, and oral surgeons, and dental laboratories. We also sell through sales agents and distributors in certain countries. In addition, we sell directly to Dental Support Organizations ("DSOs") who contract with dental practices to provide critical business management and support including non-clinical operations, and we sell products used by dental laboratories who manufacture or customize a variety of products used by licensed dentists to provide oral health care. We sell our Consumer Products online through our corporate website and large e-commerce websites.

Our clear aligners are sold under the Invisalign® brand name. Our Invisalign system is intended mainly for the treatment of malocclusions and is designed to help dental professionals achieve the clinical outcomes that they expect and the results patients desire. To date, over 12 million people worldwide have been treated with our Invisalign system. We received 510(k) clearance from the United States ("U.S.") Food and Drug Administration ("FDA") to market the Invisalign system in 1998. In order to provide Invisalign treatment to their patients, orthodontists and GPs must initially complete an Invisalign training course.

Our iTero intraoral scanner is used by dental professionals and/or labs and service providers for restorative and orthodontic digital procedures as well as Invisalign case submissions. To date, over 68,000 iTero scanners have been sold. We received 510(k) clearance in the U.S. for the caries detection feature of the iTero Element 5D in 2020. Our Systems and Services products, which includes our iTero intraoral scanners, are primarily sold through our direct sales force and through sales agents and distributors in certain countries and directly to DSOs.

Our exocad CAD/CAM software products provide restorative dentistry, implantology, guided surgery, and smile design to dental labs and dental practices through fully integrated workflows, paving the way for new, cross-disciplinary dentistry in labs and at chairside. There are over 200 exocad strategic distribution partners and over 47,000 software licenses installed worldwide.

Clear Aligner Segment

Malocclusion and Traditional Orthodontic Treatment

Malocclusion is one of the most prevalent clinical dental conditions, affecting approximately 60% to 75% of the global population. Annually, approximately 21 million people globally elect treatment by orthodontists. Today, most orthodontic patients continue to have their malocclusions treated with the use of traditional 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 the treatment, the dental professional may recommend the patient use a retainer appliance. Of the 21 million cases started, we estimate that approximately 90% or 19 million could be treated using our Invisalign system. In addition, globally approximately 500 million people with malocclusion could benefit from straightening their teeth. This represents a significant opportunity for us as we expand the market for orthodontics by training more doctors, including GPs as well as orthodontists, educating more consumers about the benefits of straighter teeth using the Invisalign system and connecting consumers with an Invisalign-trained doctor of their choice.

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. The Invisalign system offers a range of treatment options, specialized services, and access to proprietary software for treatment visualization and is comprised of the following phases:

Diagnosis and transmission of treatment data. An Invisalign trained dental professional prepares an online prescription form on our Invisalign Doctor Site and submits the patient's records, which include a digital intraoral scan or a polyvinyl-siloxane ("PVS") impression of the relevant dental arches, photographs of the patient and, at the dental professional's election, x-rays of the patient's dentition. Intraoral digital scans may be submitted through Align's iTero scanner or certain third-party scanners capable of accurately interfacing with our systems and processes. Globally, more than 85% of Invisalign system case submissions are now submitted via digital scan, increasing the accuracy of treatments, reducing the time from prescription submission to patient receipt, and decreasing the carbon footprint resulting from the shipment of the materials used to form PVS impressions to the doctors and shipping those PVS impressions back to us. Additionally, it is during this stage that exocad's CAD/CAM software platform can be used to identify, assess and assist doctors and dental labs to collaborate on any needed ortho-restorative treatment options through comprehensive interdisciplinary workflows.

Computer-simulated treatment plan. Using the digital scans or PVS impressions, certain doctor preferences and digital data provided, we generate a proposed custom, three-dimensional treatment plan, called a ClinCheck® treatment plan using proprietary software we have developed through significant, ongoing investments over more than 20 years. A patient's ClinCheck treatment plan simulates desired tooth movement in stages and details the timing and placement of any features or attachments to be used during treatment. Attachments are tooth-colored "buttons" that are sometimes used to increase the biomechanical force on a specific tooth or teeth in order to affect the desired movement(s).

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

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

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

Clear Aligner Products

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

Malocclusion	Very Mild	+	Moderate	-	Severe
Product	Invisalign Express Package	Invisalign Lite Package	Invisalign Go Limited Movement (GP)	Invisalign Moderate Packages (& Invisalign Go Plus)	Invisalign Comprehensive Packages
Treatment Stages*	7	14	20	20-26	As many as required
Clinical Scope	Relapse and minor movement, anterior esthetic alignment	Class I, mild crowding/spacing, non- extraction, pre-restorative	Class I, no anterior / posterior correction, mild to moderate crowding, spacing, non-extraction, pre-restorative Tooth movement from 2nd premolar to 2nd premolar (5x5)	Class I, mild Class II, mild to moderate crowding/spacing, mild anterior / posterior and vertical discrepancies, pre- restorative, (Go Plus tooth movement from 1 st molar to 1 st 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 treatment plans described above provide dental professionals with the option to order additional aligners if the patient's treatment deviates from the original treatment plan. The number and timing of additional aligner orders are subject to certain requirements noted in our terms and conditions.

<u>Comprehensive Products - Invisalign Treatment Options:</u>

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 Invisalign 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 seven and ten years, who frequently have a mixture of primary/baby and permanent teeth. Invisalign First Phase 1 treatment provides early interceptive orthodontic treatment, traditionally done through arch expansion, or partial metal braces, before all permanent teeth have erupted. Invisalign First Phase 1 clear aligners are designed specifically to address a wide range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition and predictable dental arch expansion. Our Invisalign First Comprehensive Phase 2 Package is complementary to 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.

<u>Non-Comprehensive Products - Invisalign Treatment Options:</u>

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

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

Feature Enhancement / New Products

Invisalign G8 with SmartForce® *Activation*. Broadly released in early 2021, Invisalign G8 with SmartForce Aligner Activation is a clear aligner biomechanical innovation designed to optimize tooth movements and further improve predictability for frequently treated crowding, crossbite, and deep bite cases through the targeted application of force to teeth through surface contours on the aligners that help control the location, direction and intensity of tooth movement.

New Invisalign Innovations in Treatment Planning for Align Digital Platform. Released in early 2022, the new Invisalign system innovations as a part of the Align digital platform is a combination of software, systems and services designed to provide a seamless experience and workflow that integrates and connects all users – doctors, labs, patients and consumers. These new innovations include ClinCheck Live Update for 3D controls, the Invisalign Practice App, Invisalign Personalized Plan and Invisalign Smile Architect.

Non-Case Products:

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

Retention. We offer up to four sets of custom clear aligners called Vivera retainers made with proprietary material strong enough to maintain tooth position and correct minor relapse, if necessary, as well as Invisalign retainers. Retainers are generally available for doctors to offer to any of their patients, whether they use the Invisalign system or other products, including wires and brackets. In select markets, we also offer single set retainers. Further, in the third quarter of 2021, we announced a multi-year supply and distribution agreement with Ultradent Products to allow Invisalign trained doctors to exclusively offer a professional whitening system using Ultradent's Opalescence PF whitening system with Vivera retainers.

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

SmartTrack Aligner Material:

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

Systems and Services Segment

Intraoral scanning is a rapidly evolving technology that is having a substantial impact on the practice of dentistry. By enabling the dental practitioner to create a 3D image of a patient's teeth (digital scan) using a handheld intraoral scanner, digital scanning is faster, more efficient, precise and comfortable for patients. Beginning patient care with the early usage of our iTero intraoral scanners and combining the results with digital workflows designed to assist doctors and patients visualize and evaluate various treatment options with detailed imagery and CAD/CAM solutions is helping patients decide to undergo treatment and improve treatments, outcomes and satisfaction. The accuracy of digitally scanned models substantially reduces the rate of restoration "remakes," meaning patients are recalled less often and the appointment time for the restoration is shorter because of fewer adjustments, increasing overall patient satisfaction. Digital models also reduce the carbon footprint associated with the shipping of the materials used to create PVS impressions, the shipping of those impressions and their disposal. Moreover, the digital model file can be used for various procedures and services including fabrication of physical dental models for use by labs to create restorative units such as veneers, inlays, onlays, crowns, bridges and implant abutments; digital records storage; aid to caries detection; orthodontic diagnosis; orthodontic retainers and appliances; and Invisalign digital impression submission.

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

Our iTero Element 5D imaging system is the first integrated dental imaging system that simultaneously records 3D, intraoral color camera images and near imaging ("NIRI") technology and enables comparison over time using the iTero TimeLapse technology. NIRI technology, included in our iTero Element 5D and 5D Plus Imaging Systems, aids in detection and monitoring of interproximal caries lesions above the gingiva without using harmful radiation. The iTero Element 5D Imaging System is available in the U.S., Canada, China, and the majority of EMEA and select APAC and LATAM countries

and is pending regulatory approval in others.

The iTero Element Plus Series of intraoral scanners and imaging systems was introduced in the first quarter of 2021 and offers restorative and orthodontic digital workflows that include enhanced visualization for optimized patient experience, including a fully integrated 3D intraoral camera in certain models,; seamless scanning with reduced processing time, artificial intelligence-based features, and, in certain models, NIRI technology.

Services and Ancillary Products. Our services include subscription software, disposables, rentals, and pay per scan as well as exocad's CAD/CAM software solutions that integrate workflows to dental labs and dental practices.

Restorative software for iTero scanners and imaging systems. Our Restorative software is designed for GPs, prosthodontists, periodontists and oral surgeons and includes restorative workflows providing the ability to send digital impressions to the lab of their choice and communicate seamlessly with external treatment planning, custom implant abutment, chairside milling and laboratory CAD/CAM systems such as through our exocad Connector. iTero intraoral scans can enhance the accuracy and precision of a doctor's downstream restorative process.

Orthodontic software for iTero scanners and imaging systems. Our iTero software is designed for orthodontists for digital records storage, orthodontic diagnosis, and for the fabrication of printed models and retainers.

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 general dentists 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.

Ancillary Products. We sell disposable sleeves for the wand and other ancillary products for the iTero scanner.

iTero Models and Dies. An accurate physical model and dies are manufactured based on the digital scan and sent to the laboratory of the dentist's choice for completion of the needed restoration. The laboratory also has the option to export the digital file for immediate production of coping and full-contour restorations on their laboratory CAD/CAM systems. The laboratory then completes the ceramic buildup or staining and glazing and delivers the end result - a precisely fitting restoration.

Third-Party Scanners and Digital scans. We accept case submissions for our clear aligner products in two ways: (1) PVS impressions of patients' teeth or (2) intraoral scans of their teeth. With respect to intraoral scans, we accept scans from iTero scanners and certain third-party scanners that have an interoperability relationship with our systems and processes.

iTero Applications and Tools

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.

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

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. We also recently introduced our 5D Photo uploader enhanced workflow that simplifies the process for submitting images needed for treatment planning.

Other proprietary software mentioned in this Annual Report on Form 10-K, such as software embedded in our iTero

scanners, ClinCheck and ClinCheck Pro software, the Invisalign Doctor Site, and feature enhancements included as part of the Invisalign system are not sold separately, nor do they contribute as individual items to revenues.

Business Strategy

Our technology and innovations are designed to meet the demands of today's patients with treatment options that are convenient, comfortable, and affordable, while helping to improve 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 the best possible treatment outcomes and experiences to millions of people around the world. We achieve this by focusing on and executing to our strategic growth drivers:

- International Expansion. We continue increasing our presence globally by making our products available in more countries to more customers. In 2021, the number of international doctors trained to prescribe treatment using the Invisalign system grew by approximately 21% compared to 2020. We continue expansion of our sales and marketing by reaching into new countries and regions, including new areas within Africa. By the end of 2021, we were selling directly or through authorized distributors in more than 100 countries. As our business continues to grow in both number of new Invisalign trained doctors and customer utilization, we support that growth through targeted investments such as increasing headcount, 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. For instance, for China and other APAC markets, we now primarily fabricate our clear aligners in Ziyang, China, and we perform digital treatment planning and interpretation for restorative cases worldwide, including in Costa Rica, China, Germany, Spain, Poland, and Japan, among others. In 2021, we announced similar plans to open a clear aligner manufacturing facility in Wroclaw, Poland. Expected to begin serving doctors during the first half of 2022, the new manufacturing facility will be our third aligner fabrication facility and allow us to more quickly and effectively serve tens of thousands of customers throughout EMEA. 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 2022 by investing in resources, infrastructure and initiatives that help drive Invisalign treatment growth, our intraoral scanners as the preferred scanning technology for digital dental scans, and our exocad CAD/CAM software as the solution of choice for dental labs in existing and new international markets.
- *GP Adoption*. We want to enable GPs, who have access to a large patient base, to more easily identify potential cases they can treat with the Invisalign system, monitor patient progress or, if needed, help refer cases to an orthodontist while providing high-quality restorative, orthodontic and dental hygiene care. We believe success with GPs can be achieved through doctor training and clinical education, by offering digital tools such as the iTero scanner and products like Invisalign Go treatment that address the distinctive needs of GP patients, all delivered by sales and marketing personnel specifically focused on the unique needs of this customer category. We encourage GPs to scan every patient with intraoral scanners that are without harmful radiation as a means to diagnose and treat patients over time and as an opportunity to drive future demand for their services and the Invisalign system. To support our belief in the benefits of using our iTero scanners, in October 2021 we announced the findings of a clinical study that validates and demonstrates that the NIRI technology of the iTero Element 5D imaging system was 66% more sensitive than bitewing x-ray radiography for detection of interproximal lesions, without the use of harmful radiation.
- Patient Demand & Conversion. Our goal is to make the Invisalign brand a highly recognized name brand worldwide by creating awareness for Invisalign treatment among consumers and motivating the potential 500 million patients who can benefit from treatment of malocclusion to seek treatment using the Invisalign system. We accomplish this through an integrated consumer marketing strategy that includes television, media, social networking and event marketing and strategic alliances with professional sports teams, as well as educating patients on treatment options and directing them to high volume Invisalign trained doctors. We further support our doctor customers as they adopt digital dentistry through programs such as the Align Digital and Practice Transformation ("ADAPT"). ADAPT is an expert and independent fee-based business consulting service designed to optimize dental operational workflow and processes to enhance patients' experiences and customer and staff satisfaction with the goal of increasing practice growth and efficiencies. To further drive consumer awareness, in 2021 we began offering additional dental-related Consumer Products under the Invisalign brand name available in certain e-commerce channels in the U.S.
- *Orthodontist Utilization*. We continue to innovate and increase product applicability and predictability to address a wide range of cases, from simple to complex, thereby enabling doctors to confidently diagnose and treat children and

adults with the Invisalign system. This is especially important to treating teenage patients who make up the largest portion of the 21 million annual orthodontic case starts each year. We also continue to make improvements to our Invisalign treatment software, ClinCheck Pro software, designed to deliver an exceptional user experience and increase treatment control to help our 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 and restorative dentistry by providing doctors with greater flexibility, consistency of treatment preferences and real-time treatment plan access and modification capabilities.

Manufacturing and Suppliers

We have manufacturing facilities located in Juarez, Mexico, where we conduct our aligner fabrication, distribution, and certain services and in Ziyang, China, where we fabricate aligners primarily for China and other APAC markets. In addition, we produce our handheld intraoral scanner wand, perform final scanner assembly and repair our scanners at our facilities in Ziyang, China and Or Yehuda, Israel and service and repair certain scanners in Juarez, Mexico. In the second quarter of 2021, we announced the start of a multi-million dollar project to bring operational facilities closer to our customers through the expansion of our manufacturing operations in Wroclaw, Poland. Expected to begin serving doctors during the first half of 2022, the new aligner fabrication facility will be our third and allow us to more quickly and effectively serve tens of thousands of customers throughout EMEA. Additionally, in the third quarter of 2021, we opened our multi-story iTero scanner and services facilities in Petach Tikva, Israel to further the design and development of our portfolio of iTero intraoral scanners, imaging systems and services.

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

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

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

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

Sales and Marketing

Our sales and marketing efforts are focused on increasing adoption and utilization of the Invisalign system and Vivera retainers by orthodontists and GPs worldwide and integrating the iTero scanner and exocad CAD/CAM products into dental labs and practices. The scanner is an important component to the customer experience and is central to a digital approach as well as overall customer utilization of Invisalign treatments. 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 to support orthodontists and GPs separately, allowing highly trained and specialized personnel to serve each customer category, thereby increasing our focus and effectiveness on both. We continue to expand in existing markets through targeted investments in sales resources, professional marketing and education programs. Additionally, our consumer marketing programs are designed to create awareness and educate consumers on the benefits of Invisalign treatment and Vivera retainers, including where they can find a trained doctor to provide treatment.

We provide training, marketing and clinical support to orthodontists and GPs. As of December 31, 2021, we had approximately 122,500 active Invisalign trained doctors. We define doctors as active if they have submitted at least one case in the prior 12-month period.

Research and Development

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

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

In an effort to demonstrate the broad treatment capabilities of the Invisalign system, various clinical case studies and articles have been published that highlight the clinical applicability of Invisalign treatment to malocclusion cases, including those of severe complexity. Similarly, various studies have also been published demonstrating the capabilities of our scanners, including advanced features such as our NIRI technology. We undertake precommercialization 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 12th year in 2021, our donations to the American Association of Orthodontists Foundation and our partnership with MedTech Innovator Asia Pacific, a nonprofit startup accelerator for the medical technology industry that connects healthcare industry leaders with innovative medical technology startups for mentorship and support.

Intellectual Property

We believe our intellectual property portfolio represents a substantial business advantage. As of December 31, 2021, we had 642 active U.S. patents, 724 active foreign patents, and 736 pending global patent applications. Our active U.S. patents expire between 2022 and 2040. When patents expire, we lose the protection and competitive advantages they provided, which could negatively impact our operating results; however, as we continue to pursue new innovations, we seek intellectual property protection for new inventions and know-how through U.S. and foreign patent applications and non-disclosure agreements. We also seek to protect our software, documentation and other written materials under trade secret and copyright laws. We furthermore have a broad and diverse trademark portfolio that we use to highlight and protect our universally recognized brands. Information regarding risks associated with our proprietary technology and our intellectual property rights may be found in *Item 1A* of this Annual Report on Form 10-K under the heading "*Risk Factors*."

Seasonal Fluctuations

General economic conditions impact our business and financial results, and we have historically experienced seasonal trends within our two operating segments, customer channels and the geographic locations that we serve. Sales of the Invisalign system are often weaker in Europe, especially southern European countries during the summer months due to our customers and their patients being on holiday and seasonally higher in China during the third quarter. Similarly, other international holidays like Lunar New Year can impact our sales in APAC. In North America, summer is typically the busiest season for orthodontists with practices that have a high percentage of adolescent and teenage patients as many parents want to get their teenagers started in treatment before the start of the school year; however, many GPs are on vacation during this time and therefore tend to start fewer cases. For our Systems and Services segment, capital equipment sales are often stronger in the fourth calendar quarter. Consequently, these seasonal trends have caused and may continue to cause fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates. Moreover, the COVID-19 pandemic with its consequent office closures or capacity constraints imposed to curtail the spread of the virus and its variants, and the easing and

reimplementation of those restrictions, has exacerbated the timing and extent of seasonal patterns and it remains unclear when or if they will return to historical norms.

Competition

Our clear aligner products compete directly against traditional orthodontic treatments that use metal brackets and wires and increasingly against clear aligner products manufactured and distributed by various companies, both within and outside the U.S. Although the number of competitors varies by segment, product, geography and customer, they include new and well-established regional competitors in certain foreign markets, as well as larger companies or divisions of larger companies with substantial sales, marketing, research and financial capabilities. Due in part to the expiration of certain of our clear aligner key patents beginning in 2017 and the significant benefits of clear aligner treatment over traditional brackets and wires, competition in the clear aligner market is increasing. In addition, corresponding foreign patents began expiring in 2018 which has increased competition outside the U.S. These competitors include existing larger companies in certain markets who have the ability to leverage their existing channels in the dental market to compete directly with us, direct-to-consumer ("DTC") companies that provide clear aligners requiring little or no in-office care from trained and licensed doctors, and doctors themselves who can manufacture custom aligners in their offices using modern 3D printing technology. Unlike our DTC competitors, we are committed to doctors being at the core of our business strategy, and Invisalign treatment requires a doctor's prescription and an in-person physical examination of the patient's dentition before treatment can begin.

Additionally, we face competition in the emerging and rapidly evolving markets for intraoral scanners and software solutions, including CAD/CAM. The global intraoral scanner market is very dynamic with participants spanning from traditional dental conglomerates to companies dedicated primarily to scanner development and sales with new entrants from South Korea and China playing larger roles. Information regarding risks associated with increased competition may be found in *Item 1A* of this Annual Report on Form 10-K under the heading "*Risk Factors*."

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

Government Regulation

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

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

We are also subject to various laws around the world that govern interactions with our customers as healthcare professionals or government officials. The laws govern different interactions and may include prohibiting improper influence of or payments to healthcare professionals and government officials, setting out rules for when and how to engage healthcare professionals as our vendors, requiring price reporting regulations, requiring proper and on label promotion, sale and marketing

of our products and services, importation and exportation of our products, the operation of our facilities and distribution of our products, and disclosure of payments to healthcare professionals and entities. As we expand our operations footprint, countries to which we sell and invest in new business models, compliance with applicable laws becomes more complex and the general trend is toward increasingly stringent oversight and enforcement.

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

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

In addition, we must comply with numerous data protection and storage requirements that span from individual state and national laws in the U.S., China and other countries, to multinational requirements in the EU, including laws that regulate or restrict cross border data transfers. In the U.S., we must comply with final regulations implementing amendments to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the associated HIPAA Security Rule. We are also required to comply with the California Consumer Privacy Act and are preparing for a number of state-level laws and bills in the U.S., including the California Privacy Rights Act of 2020. In the EU, we must comply with the General Data Protection Regulation, which serves as a harmonization of European data-privacy law and the Swiss Federal Act on Data Protection, where Align has its EMEA headquarters. In LATAM markets, we must comply with Brazil's Lei Geral de Proteção de Dados. Meanwhile, the APAC and EMEA regions have also seen rapid development of privacy laws including Turkey, Morocco, Ghana, India, Russia, China, South Korea, Singapore, Hong Kong, Israel, and Australia.

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

Human Capital

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

As of December 31, 2021, we had approximately 22,540 employees, an increase of approximately 25% and 55% over December 31, 2020, and December 31, 2019, respectively. Included among our employees as of December 31, 2021, were approximately 14,200 in manufacturing and operations, 4,600 in sales and marketing (which includes customer care), 1,375 in research and development, and 2,365 in general and administrative functions. We are a global organization with the majority of our employees in direct-labor roles in our manufacturing and clinical treatment planning facilities. Set forth in the following paragraphs are some of the most important elements of our culture and commitment to our employees.

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

To demonstrate our commitment to our environmental, social and governance ("ESG") efforts, our Board has delegated ESG oversight responsibility to our Nominating and Governance Committee. In 2021, our Board took further steps to support ESG by amending the charter of our Compensation Committee to specifically empower the committee to oversee our diversity, equity and inclusion initiatives.

Diversity. Fostering diversity and encouraging inclusion in the workplace makes Align a more welcoming and enjoyable place to work. Our products and services are used broadly across age groups, gender identities, races, ethnicities, and cultures, so we aim to build a workforce that optimally reflects this diversity. We believe our success continues to be driven by our focus on integrating employees of all different backgrounds, orientations, beliefs, perspectives and capabilities into our workforce. Our approximately 22,540 employees bring a positive mix of ethnic and culturally diverse backgrounds to the more than 40 different countries in which we operate. Our management team is comprised of diverse individuals from varying countries and nationalities and who are committed to promoting and encouraging the health and well-being of our employees at work, at home and in society in general.

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

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

Community. We provide opportunities for and actively encourage employees to support local charitable organizations through volunteerism, team building, and donation and matching programs and are extremely proud of the generosity and dedication of our employees especially during our annual Month of Smiles initiative in October. In addition, through our Align Foundation, we support organizations whose visions closely align with our own, including Operation Smile and America's ToothFairy. We also provide product donations to the dental community to help patients in need of a healthy, beautiful smile. 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.

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 our 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 proven successful, resulting in numerous awards for our positive work environment and culture. In 2021 alone, we were recognized by:

- Forbes as one of their World's Best Employers in 2021
- Great Places to Work and Best Places to Work based on our employee-validated great workplaces in the following countries Brazil, Canada, China, Costa Rica, Germany, India, Poland, Singapore, U.S., and Vietnam
- Computerworld as Best Place to Work in IT, based in its survey of organizations across the U.S. to identify those that provide the best benefits and
 amenities for IT professionals

Training and Professional Development. Training is an integral part of developing and retaining our employees and creating a culture of leadership within the Company. In 2021, 54% of our employees engaged in some form of professional development activities. The U.S. Department of Labor uses the benchmark of 23% as a best practice standard for companies.

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

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

Employees are encouraged to participate in a variety of Company-provided learning resources through our corporate platform Align University. The platform offers a broad range of development tools with more than 1,000 courses available in multiple languages to serve our many employees globally, including professional development events, external training

programs based on individual needs, business-led enterprise leader learning events, diversity and inclusion, online business skills courses and onsite classroom events. This is in addition to opportunities offered for job development such as our Early Leader program as well as the Align Leadership Journey, for which our program on creativity and curiosity was recognized with a Brandon Hall Innovation Award, and other management skills training and trainings that create opportunities for advancement.

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

We are furthermore committed to pay equity practices. We regularly review our pay equity practices, none of which have shown any systemic differences in pay or pay practices.

Recognizing that financial security is as important to the emotional health and well-being of our employees as physical precautions against the COVID-19 virus and its many variants, we committed at the outset of the pandemic to protect our employees and their families financially by declaring we would not furlough, lay off or cut employee pay. We have honored this commitment throughout the pandemic.

Health and Safety. Our employees are essential to us as a business and their health and well-being is critical to our success and their continuing achievements. Our objective is to prevent injuries and occupational diseases by focusing first and foremost on creating and maintaining environments that are safe. We therefore offer a wide variety of robust programs and initiatives designed to promote the overall health and welfare of all our employees and their families. In addition to the compensation and benefits listed above, we offer family support services, healthcare initiatives and career services support, among many others. In response to the COVID-19 pandemic and the impacts of remote working, we have encouraged employees to take time away from work to be with their families and implemented initiatives to promote better work-life balance. In addition, we have several health and safety programs in place to help protect our employees. For instance, we have training programs and courses that employees exposed to particular risks are required to take and update periodically. Examples include hazardous material training, emergency response and evacuation training, ergonomics training, biohazard and personal protective equipment training, and, more recently, COVID-19 related safety training.

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

Available Information

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

Information about our Executive Officers

The following table sets forth certain information regarding our executive officers as of February 25, 2022:

Name	Age	Position
Joseph M. Hogan	64	President and Chief Executive Officer
John F. Morici	55	Chief Financial Officer and Executive Vice President, Global Finance
Julie Coletti	54	Executive Vice President, Chief Legal and Regulatory Officer
Stuart Hockridge	50	Executive Vice President, Global Human Resources
Emory M. Wright	52	Executive Vice President, Global Operations

Joseph M. Hogan has served as our President and Chief Executive Officer and as a member of our Board of Directors since June 2015. Prior to joining us, Mr. Hogan was Chief Executive Officer of ABB Ltd., a global power and automation technologies company based in Zurich, Switzerland from 2008 to 2013. Prior to working at ABB, Mr. Hogan worked at General Electric Company (GE) in a variety of executive and management roles from 1985 to 2008, including eight years as Chief Executive Officer of GE Healthcare from 2000 to 2008.

John F. Morici served as our Chief Financial Officer beginning in November 2016. His title was changed to Chief Financial Officer and Senior Vice President, Global Finance in February 2018 and was changed again in February 2022 to Chief Financial Officer and Executive Vice President. Prior to joining us, Mr. Morici was at NBC Universal from 2007 to 2016 where he held several senior management positions in their Universal Pictures Home Entertainment U.S. and Canadian business, including Chief Financial Officer, Chief Operating Officer, and most recently, Executive Vice President and Managing Director from 2014 to 2016. Prior to NBC Universal, Mr. Morici was in various senior financial management positions at GE Healthcare from 1999 to 2007, including Chief Financial Officer for its Diagnostic Imaging and Global Products units from 2002 to 2003.

Julie Coletti served as our Senior Vice President, Chief Legal and Regulatory Officer from May 2019 until February 2022 when her title was changed to Executive Vice President, Chief Legal and Regulatory Officer. Ms. Coletti joined Align in May 2018, serving as Vice President and Associate General Counsel, Strategic Commercial Affairs until her promotion in 2019. Prior to Align, Ms. Coletti was Vice President, Global General Counsel and Chief Compliance Officer for Danaher Corporation, a healthcare, environmental and industrial equipment manufacturer, in its dental platform business. Before Danaher, Ms. Coletti served in various senior legal management positions, including as Vice President, Chief Legal Officer and Corporate Secretary at Bayer HealthCare's MEDRAD/Radiology and Interventional Division, a leading manufacturer of pharmaceuticals and medical devices for imaging and interventional cardiology.

Stuart Hockridge served as our Vice President, Global Human Resources beginning in May 2016. His title was changed to Senior Vice President, Global Human Resources in February 2018 and was changed again in February 2022 to Executive Vice President, Global Human Resources. Prior to joining us, Mr. Hockridge was Senior Vice President of Talent at Visa Inc. from 2013 to 2016. Prior to Visa, Mr. Hockridge held a number of human resource management positions at GE Healthcare from 2002 to 2012 leading HR processes both globally and for various divisions.

Emory M. Wright served as our Vice President, Operations beginning in December 2007. His title changed to Senior Vice President, Global Operations in February 2018 and was changed again in February 2022 to Executive Vice President, Global Operations. He has been with us since March 2000 predominantly in manufacturing and operations roles including Vice President, Manufacturing and was General Manager of New Product Development. Prior to joining Align, from 1999 to 2000, Mr. Wright was Senior Manufacturing Manager at Metrika, Inc. a medical device manufacturer. Mr. Wright also previously served as Manager of Manufacturing and Process Development for Metra Biosystems Inc.

Item 1A. Risk Factors.

The following discussion is divided into two sections. The first, entitled "Risks Relating to our Business Operations and Strategy," discusses some of the risks that may affect our business, results of operations and financial condition. The second, captioned "General Risk Factors," discusses some of the risks that apply generally to companies and to owning our common stock, in particular. You should carefully review both sections, as well as our consolidated financial statements and notes thereto and other information appearing in this Annual Report on Form 10-K, for important information regarding these and other risks that may affect us. The order we have chosen to list the risks below or the sections in which we have identified them should not be interpreted to mean we deem any risks to be more or less important or likely to occur or, if any do occur, that their impact may be any less significant than others. These risk factors should be considered in connection with evaluating the

forward-looking statements contained in this report because they could cause our actual results and conditions to differ materially from those statements. Before you invest in Align, you should know that investing involves risks, including those described below. The risks below are not the only ones we face. If any of the risks actually occur, our business, financial condition and results of operations could be negatively affected, the trading price of our common stock could decline, and you may lose all or part of your investment.

Summary of Risk Factors

The following is a summary of the risks that are more fully described below in this "Risk Factors" section:

Risks Relating to our Business Operations and Strategy

- Our results of operations have been materially adversely affected by global and regional efforts to mitigate the spread of COVID-19 and we expect this will continue in as yet unknown ways and to varying degrees as the virus evolves and circumstances dictate.
- Our net revenues are dependent primarily on our Invisalign system and iTero scanners and any decline in sales or average selling price of these products, for any reason, may adversely affect net revenues, gross margin and net income.
- Competition in the markets for our products is increasing and we expect aggressive competition from existing competitors, other companies that
 may introduce new technologies in the future and customers who alone or with others create orthodontic appliances and solutions or other
 products or services that compete with us.
- An increasingly larger portion of our total revenues are derived from international sales and we are dependent on our international operations, which exposes us to foreign operational, political, military and other risks that may harm our business.
- Demand for our products may not increase as rapidly as we anticipate or may decrease due to a variety of factors, including changing consumer
 demand, inflation, weakness in general economic conditions, recessions and resistance to non-traditional treatment methods.
- Our success depends on our ability to develop, successfully introduce, achieve market acceptance of, and manage new products and services.
- As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity and operational inefficiencies at our manufacturing and treat facilities.
- Our products and information technology systems are critical to our business. Issues with product development or enhancements, IT system
 integration, implementation, updates and upgrades along with security and data protection risks have previously and could again in the future
 disrupt our operations, which could have a material adverse impact on our business and operating results.
- If we are unable or fail to protect our customer or patient information or if we are unable to comply with applicable privacy, security and data protection laws, our operations may be severely adversely impacted, patient care could suffer, we could be liable for related damages, and our business, operations and reputation could be harmed.
- If we fail to sustain or increase revenue growth while controlling expenses, our profitability may decline.
- Our operating results have and will continue to fluctuate in the future, which makes predicting the timing and amount of our revenues, costs and expenditures difficult.
- A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could disrupt our supply chain and cause a decline in our net revenues or a reduction in our earnings.
- If we fail to accurately predict our volume growth, hire too many or too few technicians, or manufacture too many or too few products, the
 delivery time for our products could be delayed or our costs may exceed our revenues, each of which could adversely affect our results of
 operations.
- We are dependent on our marketing activities to deepen our market penetration and raise awareness of our brand and products, which may not prove successful or may become less effective or more costly to maintain in the long term.
- Our success depends in part on our proprietary technology, and if we fail to successfully obtain or enforce our intellectual property ("IP") rights, our competitive position may be harmed. Litigating claims of this type is costly and could distract our management and cause a decline in our results of operations and stock price.
- If we or any vendors on whose products or services we rely for our products and services infringe the patents or IP rights of other parties or are subject to a patent infringement claim, our ability to grow our business may be severely limited.
- Obtaining approvals and complying with governmental regulations, particularly those related to personal healthcare information, financial
 information, quality systems and data privacy, is expensive and time-consuming, and any failure to obtain or maintain approvals or comply with
 regulations regarding our products or services or the products and services of our suppliers or customers could materially harm our sales, result in
 substantial penalties and cause harm to our reputation.
- We are highly dependent on third-party suppliers, some of whom are sole source suppliers, for certain key machines, components and materials, and our business and operating results could be harmed if supply is restricted or ends or the price of raw materials used in our manufacturing process increases.

- We rely on highly skilled personnel and, if we fail to attract, motivate, train or retain highly skilled personnel, it may be more difficult to grow effectively and pursue our strategic priorities.
- We use distributors for a portion of the importation, marketing and sales efforts related to our products and services, which exposes us to risks that may be harmful to our sales and operations, including that these distributors do not comply with applicable laws or our internal procedures.
- 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.
- Compliance with current or future environmental, social, and governance ("ESG") laws may materially increase our costs, expose us to potential liability and otherwise materially impact our business.

General Risk Factors

- We rely on our personnel and, if we fail to attract, motivate or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities.
- Business disruptions could seriously harm our financial condition.
- Changes in, or interpretations of, accounting rules and regulations, could result in unfavorable accounting charges.
- 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 have an adverse effect on our stock price.
- We are exposed to fluctuations in currency exchange rates and inflation, each of which could negatively affect our financial condition and results
 of operations.
- If we fail to manage our exposure to global financial and securities market risks successfully, our operating results and financial statements could be materially impacted.
- If our goodwill or long-lived assets become impaired, we may be required to record a significant charge to earnings.
- Our effective tax rate may vary significantly from period to period.
- New tax laws and practice, changes to existing tax laws and practice, or disputes regarding the positions we take regarding tax laws, could
 negatively affect our provision for income taxes as well as our ongoing operations.
- We have in the past and may again in the future invest in or acquire other businesses, products or technologies which may require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.
- Historically, the market price for our common stock has been volatile.
- We cannot guarantee that we will continue to repurchase our common stock in the future, and any repurchases that we may make may not achieve our desired objectives.
- Future sales of significant amounts of our common stock may depress our stock price.
- Increased scrutiny of our ESG policies and practices have and will likely continue to result in additional costs and risks, and may adversely impact our reputation, employee retention, and willingness of customers and suppliers to do business with us.

Risks Relating to our Business Operations and Strategy

Our results of operations have been materially adversely affected by global and regional efforts to mitigate the spread of COVID-19 and we expect this will continue in as yet unknown ways and to varying degrees as the virus evolves and circumstances dictate.

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

COVID-19 has created significant, widespread and unprecedented volatility, uncertainty, and economic instability, disrupting broad aspects of the global economy, our operations and the businesses of our customers and suppliers. Many of these effects continue to varying degrees and further mutated variants and outbreaks globally or regionally continue to harm recovering consumer confidence and have led to renewed implementation of harsh preventative measures by local and regional governments and businesses. Therefore, comparing our financial results for the reporting periods of 2021 to the same reporting periods of 2020 or 2019 may not be a useful means by which to evaluate the health of our business and our results of operations.

As a result of the pandemic, customer demand and doctor availability has been inconsistent and difficult to predict. Although the practices of the doctors, dental service organizations and labs that are our principal customers have largely reopened, many continue to operate at less than pre-pandemic capacities. In addition, new variants of the virus have caused unpredictable fluctuations in the number of patients seeking treatment and the number of doctors providing the services and

treatments. While the pandemic increased demand for digital solutions such as the products and solutions we offer for the dental field, it is unclear whether increased demand for our products will continue. For instance, if the use of video conferencing declines when employees return to office work environments or the availability of travel, dining, entertainment and other consumer spending categories rebound, demand for our products or the growth rates for our products may decline. These fluctuations have adversely impacted our results of operations from time to time in the recent past and are expected to continue to impact our results, particularly in the near term.

In response to the pandemic, in 2020 we implemented measures aimed at limiting its spread for the health and safety of our employees, customers, patients and the communities in which we live and work as well as in accordance with orders and decrees of governmental agencies. These measures included diagnostic screenings at our facilities, increased social distancing mandates, closures of physical offices, manufacturing and treatment planning facilities, including our U.S. corporate headquarters and regional facilities worldwide, implementing remote working where feasible, and prohibiting non-essential travel. Many of these actions remain in effect to varying degrees and we may implement new or revise existing measures as circumstances require. The actions and reactions to voluntary and involuntary protective measures have been highly disruptive to our business and may continue to be disruptive.

The rules and regulations for reopening and operating our offices will likely increase in complexity, making compliance more difficult. Furthermore, if employees perceive the protocols and requirements we implement to create a safe and effective work environment to be inadequate, overly burdensome or no longer necessary, or alternatively, if we require employees to return to the office when they prefer the safety or convenience of working from home, employees may choose to leave, productivity may decline or we may experience employee unrest, slowdowns, stoppages or other demands. Additionally, we may fail to timely meet customer demand or fulfill orders, the costs to maintain or implement protective measures or deliver our products may increase, and we may be subject to increased litigation, including product liability and occupational safety and condition claims. For further discussion or the risks related to employee satisfaction, retention and engagement see the risk factor "We rely on our personnel and, if we fail to attract, motivate or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities."

As the economic and societal impact of the pandemic continues, we are continually evaluating macroeconomic as well as industry-specific factors, including the extent our business and financial results and the business and financial results of our customers' and suppliers' have been and in the future may be impacted. The financial health and stability of businesses and consumers overall depends on numerous evolving factors, many of which we cannot control nor accurately predict. Examples include:

- the duration, scope, and severity of governmental, business and societal actions in response to the pandemic;
- the impact on worldwide economic activity, employment rates and actions taken by central banks and governments;
- customer and consumer purchasing behavior changes as pandemic-related restrictions are curtailed, lifted or reinstated, and travel and discretionary spending patterns shift;
- the response of employees, customers and suppliers to the reimplementation or easing of social distancing mandates and returning to in-office or facility working, including anxieties regarding the continuing risks of the spread of the virus or any of its variants, vaccination requirements, and other mandates that may impact employee productivity and engagement, retention or require additional costly protective measures;
- the liquidity of funds and financial stability of consumers, customers, and patients, including their willingness to purchase our products and services, delays paying for products or services, requests for extended payment terms, or payment defaults;
- disruptions and shortages impacting the cost, availability and timing of the procurement, delivery, manufacturing and overall supply chain for raw materials, components, parts and products, including semiconductor chips;
- delays and cancellations as a result of port congestion and intermittent supplier shutdowns;
- travel and gathering restrictions, including those that adversely impair or prohibit our sales personnel from interacting with customers or that limit patients from visiting their doctors or capacity limits on the number of patients doctors can see in their offices;
- actions by competitors such as price reductions, aggressive product promotions, changes in or the launch or termination of products or product lines, and mergers, consolidations and liquidations;
- the confidence of our customers and patients that our products and solutions are sanitary and safe to use;
- data privacy and cybersecurity risks from new or expanded use of remote working and/or teledentistry by our suppliers, customers, and us, including new or expanded use of online service platforms, products and solutions such as video conferencing applications, doctor, consumer and patient apps, inadequately secured computing networks, servers, software or software applications, overheard telephone conversations, viewable computer screens, stolen passwords or access information, increased phishing and other cyber threats;

- the impact of remote working arrangements on our financial reporting systems and internal control over financial reporting, including our ability
 to ensure information required to be disclosed is timely and accurately recorded, processed, summarized, reported, and communicated to
 management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required
 disclosure; and
- · diversion of management's attention as they focus on the short- and long-term ramifications of the pandemic.

The effects of the pandemic continue to linger and evolve and we cannot predict future direct and ancillary impacts on our business or results of operations, although they may have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price as well as the businesses of our customers, suppliers and economic activity generally.

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

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

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

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

- we introduce new or change existing promotions, general or volume-based discount programs, product or services bundles, or consumer rebate programs;
- · participation in any promotions or programs unexpectedly increases or decreases or drives demand in unexpected and material ways;
- our geographic, channel, or product mix shifts to lower priced products or to products that have a higher percentage of deferred revenue;
- · we decrease prices on one or more products or services in response to increasing competitive pricing pressures;
- · we introduce new or change existing products or services, or modify how we market or sell any of our new or existing products or services; or
- our critical accounting estimates materially differ from actual behavior or results.

If any of the foregoing were to occur, our net revenues, gross profit, gross margin and net income may decline.

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

The dental industry is in a period of immense and rapid digital transformation involving products, technologies, distribution channels and business models. While solutions such as our Invisalign system, iTero scanners and CAD/CAM software facilitate this transition, whether our technologies will achieve market acceptance and, if adopted, whether and when they may become obsolete as new offerings become available remains unclear.

Currently, the Invisalign system competes directly against traditional metal wires and brackets and increasingly against clear aligners manufactured and distributed by new market entrants and manufacturers of traditional wires and brackets, both within and outside the U.S., and from traditional medical device companies, laboratories, startups and, in some cases, doctors and DSOs themselves. Due in part to market opportunities and the expiration of certain of our key patents beginning in 2017, competition in the clear aligner market is increasing. The number and types of competitors are diverse and growing rapidly. They vary by segment, geography, and size, and include new and well-established regional competitors, as well as larger companies or divisions of larger companies with substantial sales, marketing, research financial capabilities, and existing dental market channels. Our competitors also include direct-to-consumer ("DTC") companies that provide clear aligners using a remote teledentistry model requiring little or no in-office care from trained and licensed doctors, and doctors and DSOs who can manufacture custom aligners in their offices using modern 3D printing technology. Large consumer product companies may also enter the orthodontic supply market.

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

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

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

An increasingly larger portion of our total revenues are derived from international sales and we are dependent on our international operations, which exposes us to foreign operational, political, military and other risks that may harm our business.

We earn an increasingly larger portion of our total revenues from international sales generated through our foreign direct and indirect operations and we expect to increase our sales and presence outside the U.S., particularly in markets we believe have high-growth potential. Moreover, we perform many of our key production steps in locations outside of the U.S. For instance, our digital treatment planning and aligner fabrication are performed in multiple international locations, including large-scale operations in Mexico, Costa Rica and China and we continue to establish additional sites closer to our international customers, such as our manufacturing facility in Poland currently under construction. Also, we maintain significant regional sales and marketing operations in Switzerland, Singapore and China along with research and development operations globally, including in the U.S., Russia, Israel and Germany. Our reliance on international operations exposes us to risks and uncertainties that may affect our business or results of operations, including:

- difficulties managing international operations, including any travel restrictions on us or our customers;
- fluctuations in currency exchange rates;
- · import and export risks, including shipping delays, cost increases, penalties, controls, license requirements and restrictions;
- controlling production volume and quality of the manufacturing process;
- the engagement in activities by our employees, contractors, partners and agents prohibited by our policies and procedures as well as international and local trade, labor and other laws such as those prohibiting bribery and corrupt payments to government officials, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010 and export control laws;
- delays, disruptions and increasing costs to us and our suppliers for raw materials or components, manufacturing, and transportation, including as a
 result of customs clearance, port congestion, workforce unrest or labor shortages, slowdowns or stoppages, unionization efforts, or disasters,
 whether natural forces or human caused;
- · increased expense of developing, testing, manufacturing and marketing localized versions of our products;
- threats, tensions, actions and responses to any social, economic, business, geopolitical, military, terrorism, or acts of war, including the possibility, threat of, imposition of, or changes in sanctions, trade restrictions and tariffs, as well as

- retaliatory military actions, sanctions, trade restrictions and tariffs particularly involving key customers, development or manufacturing markets such as China, Mexico, Russia, the Middle East, Eastern Europe or other countries;
- Some of our employees in Israel are obligated to perform annual reserve duty in the Israeli military and may be called for additional active duty under emergency circumstances which may materially impair all or a portion of our business critical to our iTero operations. Additionally, we have significant research and development activities in Russia that may be impaired should any threatened or actual military actions occur in the Ukraine or other countries. If any of these events or conditions occur, the impact to us, our employees and customers is uncertain, particularly if emergency circumstances, armed conflicts or an escalation in political instability or violence disrupts our product development, data or information exchange, payroll or banking operations, product or materials shipping by us or our suppliers and other unanticipated business disruptions, interruptions and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure. Moreover, we have developed a multi-dimensional business continuity plan designed to mitigate the impact of potential actions and reactions to a military incursion in Ukraine and other areas, but it is unclear if it will successfully and adequately mitigate against any actions taken or sanctions imposed;
- burdens of complying with a wide variety of regional and local laws, including anti-trust, fair competition and environmental laws;
- the impact of initiatives to encourage the purchase or support of domestic vendors, which can influence customers to purchase products from, or collaborate to promote interoperability of products with, companies whose headquarters or primary operations are not domestic;
- reduced IP rights protections as compared to the protections afforded under the laws of the U.S.;
- · longer customer payment cycles and greater difficulty in accounts receivable collection; and
- potential adverse tax consequences.

The potential impacts of the United Kingdom's ("UK") withdrawal from the EU are still unfolding and have impacted varying parts of its economy at different times since the withdrawal. As the UK negotiates new trade deals and implements new laws and regulations following its withdrawal, the UK's actions could, among other potential outcomes, adversely affect the tax, tax treaty, currency, operational, legal and regulatory regimes to which our businesses are subject, including those involving data privacy and the regulation of medical devices. The withdrawal could also, among other potential outcomes, disrupt the free and timely movement of goods, services, people, data and information and significantly disrupt trade. Further, uncertainty around these and related issues could lead to adverse effects on the economies and political stability of the UK, EU and the other economies in which we operate.

Should any of these factors, either individually or in combination, occur they could materially impact our international operations and adversely affect our business as a whole.

Demand for our products may not increase as rapidly as we anticipate or may decrease due to a variety of factors, including changing consumer demand, inflation, weakness in general economic conditions, recessions and resistance to non-traditional treatment methods.

Consumer spending habits are affected by, among other things, pandemics, inflation, weakness in general economic conditions, recessions, levels of employment, salaries and wage rates, debt obligations, discretionary income, consumer confidence and consumer perception of current and future economic conditions. Declines in, or uncertain economic outlooks for, the U.S. or certain international economies could adversely affect consumer spending habits which may, among other things, result in a decrease in the number of overall orthodontic and dental case starts, reduce patient traffic in dentists' offices, reduce or shift spending away from elective, non-urgent, or higher value procedures or reduce demand for dental services generally, any of which could materially adversely affect our revenues and operating results. Conversely, to the extent social distancing, travel, work and other restrictions have limited options for consumer spending, demand for our products may decline once any or all of these restrictions ease. Inflation, weakness in the global or regional economies and recessions can decrease demand for dental technologies, causing dentists to postpone investments in capital equipment, such as intraoral scanners and CAD/CAM software. In addition, Invisalign treatment represents a significant change from traditional metal wires and brackets orthodontic treatment, and customers and consumers may not find it cost-effective or preferable to traditional treatment. For instance, a number of dental professionals continue to believe the Invisalign treatment is appropriate for only a limited percentage of patients. Increased market acceptance of our products depends in part upon the recommendations of dental professionals, as well as other factors including effectiveness, safety, ease of use, reliability, aesthetics, and price compared to competing products and treatment methods.

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

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

- successfully predict and timely innovate and develop new technologies and applications with the features and functionality customers desire or expect;
- successfully and timely obtain approval or clearance of new products or services from government agencies such as the FDA and analogous
 agencies in other countries;
- cost effectively manufacture, bring to market, market, and sell new products and services offerings;
- properly forecast the amount and timing of new product demand;
- · allocate our research and development funding to products with higher growth prospects;
- ensure compatibility of our technology, services and systems with those of our customers;
- anticipate and rapidly innovate in response to new competitive products, product offerings and technologies;
- differentiate our products and product offerings from our competitors as well as other products in our own portfolio and successfully articulate the benefits to our customers;
- qualify for third-party reimbursement for procedures involving our products; and
- encourage customers to adopt new technologies and provide the needed technical, sales and marketing support to make new product and services launches successful.

If we fail to accurately predict customer needs and preferences or fail to produce viable technologies, we may invest heavily in research and development of products that do not lead to significant revenues. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs doing so and our profitability may suffer. It may be difficult to gain market share and acceptance for new or enhance products. Introduction and acceptance of new products may take significant time and effort if the products or services require doctor education and training to understand the benefits of the new products or they measure the success of a product only after using it to treat patients. For instance, it can take up to 24 months or longer to treat patients using our Invisalign system. Consequently, doctors may be unwilling to adopt our products until they successfully complete one or more cases or until more historical clinical results are available.

In addition, as part of our effort to accommodate our customers' needs and demands, we periodically introduce new business and sales initiatives, such as our commercial teeth whitening products announced in 2021. In general, our internal resources support these new businesses or sales initiatives, and we frequently provide such support without clear indications it will prove successful or be without short-term execution challenges.

As we continue to grow, we are subject to growth related risks, including risks related to excess or constrained capacity and operational inefficiencies at our manufacturing and treat facilities.

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

We continue to establish treatment planning and manufacturing facilities closer to our international customers in order to provide them with better experiences, improve their confidence in using the Invisalign system and iTero intraoral scanners to treat more patients, and provide redundancy should other facilities be temporarily or permanently unavailable. Our ability to obtain regulatory clearance and certifications for, move into, plan, construct and equip additional facilities is subject to significant risk and uncertainty, including risks related to establishing facilities, hiring and retaining employees and delays and cost overruns, any of which may be all or partially out of our control and can negatively impact our gross margin. In addition, operating facilities located in higher cost regions compared to Mexico, China and Costa Rica negatively impacts our gross margin. If the construction or transition into additional facilities is significantly delayed, if a facility is required to temporarily or permanently, partially or fully shut down, or demand for our products outpaces our ability to hire qualified personnel and effectively implement systems and infrastructure, we may be unable to fulfill orders timely, or at all, which may negatively impact our financial results, reputation and overall business.

In addition, because adapting production capacity and related cost structures to changing market conditions takes time, our facilities' capacity may at times exceed or fall short of our production requirements. For instance, as a result of the COVID-19 pandemic, sales in the final weeks of the first quarter of 2020 declined substantially and operations at our manufacturing facilities declined shortly thereafter. Then, as dental practices reopened we experienced a rapid increase in demand. These fluctuations in demand and sales have recurred several times since the first quarter of 2020 corresponding with increases in the number of people infected with COVID-19 and variants such as Delta and Omicron, and may continue to arise in the future. If product demand decreases or increases more than forecast, we could be required to write off inventory or record excess capacity charges, we may be required to purchase or lease additional or larger facilities and additional equipment, or we may be unable to fulfill customer demand in the time frames and with the quantities required, any of which may take time to accomplish, lower our gross margin, inhibit sales or harm our reputation. Additionally, if we are required to implement new or modify existing health and safety protocols to safeguard our employees, customers or their patients, productivity could decline. Production of our clear aligners and intraoral scanners are also limited by capacity constraints due to a variety of factors, including labor shortages, shipping delays, our dependency on third-party vendors for key materials, parts, components and equipment, and limited production yields. Any or all of these problems could result in the loss of customers, provide an opportunity for competing products to gain market acceptance and otherwise harm our business and financial results.

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

We rely on the efficient, uninterrupted and secure operation of our own complex information technology systems ("IT systems") and are dependent on key software of third parties embedded in our products and IT systems as well as third-party hosted IT systems to support our operations. All software and IT systems are vulnerable to damage, attack or interruption from a variety of sources. As our business has grown in size and complexity, including through the integration of acquired businesses, which to date have been smaller organizations with less-mature or less sophisticated systems, securities practices or training, the growth has placed, and will continue to place, significant demands on our operations and such systems and have increased the risk of security incidents. To effectively manage our existing operations and continue to grow, our IT systems and applications require an ongoing commitment of significant resources to maintain, protect, enhance and restore existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards, increasingly sophisticated cyber threats, and changing customer preferences. Expanded remote working and increased usage of online and hosted technology platforms by us, our customers and suppliers have increased the demands on and risks to our IT systems and personnel. Moreover, we continue to transform certain business processes, extend established processes to new subsidiaries and/or implement additional functionality in our enterprise resource planning ("ERP"), product development, manufacturing, and other software and IT systems which entails certain risks, including disruption of our operations, such as our ability to develop and update products that are safe and secure, track orders and timely ship products, manage our supply chain and aggregate financial and operational data.

System upgrades, development of new releases and enhancements require significant expenditures and allocation of valuable employee resources. Delays in integration or disruptions to our business from implementation of these new or upgraded systems could have a material adverse impact on our financial condition and operating results.

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

A significant portion of our clear aligner production is dependent on digital scans from our iTero and third-party intraoral scanners. Failures of all or any portion of ours or third-party software or other components or systems to interoperate with iTero

or third-party scanners, termination of interoperability with third-party scanners, malware or ransomware attacks, product or system vulnerabilities or defects, or a system outage for any reason have harmed our operations previously and in the future could affect materially and adversely our ability to accept scans, manufacture clear aligners or restorative procedures or treatments and services or otherwise service our customers which may, amongst other things, harm our sales, damage our reputation, adversely impact our strategic partners or result in litigation.

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

If the information we rely on to run our businesses is inaccurate or unreliable, or if the data governance controls in place fail or change, or if compliance with such controls fails, or if we fail to properly maintain, secure or restore our IT systems, or if the integrity of our products or IT systems is compromised or questioned or data is lost, or if we fail to develop new capabilities to meet our business needs in a timely manner, we could suffer operational disruptions, have customer disputes, and fail to produce timely, accurate or complete reports. We may also be required to respond to regulatory inquiries or actions, forced to defend against litigation or pay damages, penalties or fines, experience increases in operating and administrative expenses, find it necessary to recall or repair products, rebuild networks or systems, lose existing customers or strategic business partners, experience difficulties attracting new customers or implementing our growth strategies, or suffer other adverse consequences. In addition, experienced computer programmers and hackers may be able to penetrate the security features of our products, IT systems or our cloud-based software servers hosted by third parties and misappropriate, destroy or damage our confidential information or that of third parties, expose health, financial data, or other personal information of our customers and their patients, create system disruptions or cause shutdowns. Furthermore, sophisticated hardware and operating system software and applications that we either internally develop or procure from third parties may contain defects or present risks in design, development, manufacture or distribution, including "bugs," security vulnerabilities, and other problems that can unexpectedly interfere with the operation of the system or compromise or exploit the safety and security of our products, networks or data. The costs to eliminate, mitigate or recover from security problems, viruses and bugs could be significant and depending on the nature and ex

There can be no assurance that our process of improving existing or developing new products or IT systems, integrating new IT systems, protecting confidential patient health information, and improving service levels will not be delayed or that additional product or IT systems issues will not arise in the future. Failure to adequately protect and maintain the integrity of our products and IT systems and data may result in a material adverse effect on our financial position, results of operations and cash flows.

If we are unable or fail to protect our customer or patient information or if we are unable to comply with applicable privacy, security and data protection laws, our operations may be severely adversely impacted, patient care could suffer, we could be liable for related damages, and our business, operations and reputation could be harmed.

We retain confidential customer financial as well as patient health information in addition to our own proprietary information and data essential to our business operations. Therefore, it is critical that the facilities and infrastructure on which we depend to run our business and the products we develop remain secure and are also perceived by the marketplace and our customers to be secure. Despite the implementation of security features in our products and security measures in our IT systems, our products as well as the infrastructure and IT systems on which we depend are vulnerable to physical break-ins, computer viruses, programming errors or other technical malfunctions, hacking or phishing attacks by third parties, malware and ransomware, employee error or malfeasance or similar disruptive problems. For example, we have experienced cybersecurity incidents and may again in the future. Further, the frequency of third-party cyber attacks has increased since the onset of the COVID-19 pandemic. Significant service disruptions, breaches in our infrastructure and IT systems or other cybersecurity incidents could expose us to litigation or regulatory investigations, impair our reputation and competitive position, be distracting to our management, and require significant time and resources to address. Affected parties or regulatory agencies could initiate legal or regulatory action against us, which could prevent us from resolving the issues quickly or in unanticipated ways, cause us to incur significant expense and liability, or result in judicial or governmental orders forcing us to cease operations or modify our business practices in ways that could materially limit or restrict the products and services we provide. Concerns over our privacy practices could adversely affect others' perception of us and deter customers, patients and partners from using our products. In addition, patient care could suffer, and we could be liable if our products or IT systems fail

to deliver accurate and complete information in a timely manner. We have cybersecurity and other forms of insurance coverage related to a breach event covering expenses for notification, credit monitoring, investigation, crisis management, public relations and legal advice. The policy also provides coverage for regulatory action defense including oversight, investigations and disclosure obligations as well as fines and penalties, potential payment card industry fines and penalties and costs related to cyber extortion; however, damages and claims arising from such incidents may not be covered or may exceed the amount of any coverage and do not cover the time and effort we incur investigating and responding to any incidents, which may be significant.

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

In addition, we must comply with numerous data privacy and data security requirements that span from individual state and national laws in the U.S. and China to multinational requirements in the EU. For instance, China has enacted complex and highly restrictive cybersecurity, data localization, and cross border data transfer laws. In the EU, we must comply with the General Data Protection Regulation which serves as a harmonization of EU data-privacy laws, and in the U.S., we must comply with data privacy and data security provisions of the U.S. Health Insurance Portability and Accountability Act regulations. Moreover, the number of local and national governments enacting data privacy laws continues to increase and we expect this trend to continue. Maintaining compliance with these laws and regulations is costly and could require complex changes in the way we do business or provide services to our customers and their patients. Additionally, our success may be dependent on the success of healthcare providers, many of whom are comprised of individual or small operations with limited IT experience and inadequate or untested security protocols, in managing data privacy and data security requirements.

If we fail to sustain or increase revenue growth while controlling expenses, our profitability may decline.

If we are to sustain or increase profitability in future periods, we need to continue increasing our net revenues while controlling expenses. Because our business and the markets we target are evolving, it is difficult to predict our future operating results or levels of growth or declines. We have not in the past and may be unable in the future to sustain or regain our historical growth rates which may cause our profitability to decline.

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

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

- limited visibility into, and difficulty predicting from quarter to quarter, the types of procedures and level of activities in our customers' practices;
- fluctuations in the number of patients seeking treatment and the number of doctors providing services and treatment as a result of the pandemic and new variants in the virus:
- · changes in demand based on geographies, channels, or product mix;
- the level of confidence of doctors in our products and changes in the rates at which they recommend or utilize our products for their patients;
- · weakness in consumer spending and confidence, inflation, a slowdown or recession in domestic or international economies;
- higher manufacturing, delivery and inventory costs;
- unanticipated delays and disruptions in the manufacturing process caused by insufficient capacity or availability of raw materials, parts or
 components, shortages or turnover in the labor force or the introduction of new production processes, power outages or insufficient power, natural
 or other disasters, pandemics or general economic conditions impacting the solvency of vendors in our supply chain;
- competition in general and competitive developments in our target markets;

- new programs or business models, new product or services introductions or changes or modifications to existing products and services offerings, including any impacts related to the timing of orders, product mix or market cannibalization;
- changes in relationships with DSOs and distributors, including the timing of orders;
- changes in the timing of revenue recognition and changes in our average selling prices, including as a result of the timing of receipt of product
 orders and shipments, product and services mix, geographic mix, product and services deferrals, the introduction of new products and software
 releases, product pricing, bundling and promotions, pricing for fees or expenses, modifications to our terms and conditions such as payment terms,
 or as a result of new accounting pronouncements or changes to critical accounting estimates including, without limitation, those estimates based
 on such matters as our predicted usage of additional aligners;
- the creditworthiness, liquidity and solvency of our customers and their ability to timely make payments when due;
- fluctuations in currency exchange rates against the U.S. dollar;
- our inability to scale, suspend or reduce production and treatment operations based on variations in product demand;
- seasonal fluctuations, including those related to patient demographics such as the seasonality of teen treatments in the U.S., China and Europe as well as the number of doctors in their offices and their availability to take appointments;
- costs and expenditures in connection with such things as the establishment of new treatment planning and fabrication facilities, the hiring and deployment of personnel, and litigation, and the success of or changes to our marketing programs from quarter to quarter;
- · timing and fluctuation of spending around marketing and brand awareness campaigns and industry trade shows;
- · our reliance on our contract manufacturers for the production of sub-assemblies for our intraoral scanners;
- increased advertising or marketing efforts or aggressive price competition from competitors;
- · changes to our effective tax rate;
- major changes in available technology or the preferences of customers may cause our current product offerings to become less competitive or obsolete;
- · unanticipated delays or disruptions in our receipt of patient records made through intraoral scanners for any reason;
- disruptions to our business due to political, economic or other social instability or any governmental regulatory or similar actions, including the impact of epidemics and pandemics such as COVID-19, any of which results in changes in consumer spending habits, limiting or restricting patient visits to orthodontists or general practitioners, as well as any impact on workforce absenteeism;
- inaccurate forecasting of net revenues, production and other operating costs;
- investments in research and development to develop new products and enhancements; and
- · material impairments of goodwill and long-lived assets.

To respond to these and other factors, we may make business decisions that adversely affect our operating results such as modifications to our pricing policy and payment terms, promotions, development efforts, product releases, business structure or operations. Most of our expenses, such as employee compensation and lease obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations for future revenues. As a result, if our net revenues for a particular period fall below expectations, we may be unable to timely or effectively reduce spending to offset any shortfall in net revenues. Due to these and other factors, we do not believe that quarter-to-quarter comparisons of our operating results are meaningful.

A disruption in the operations of a primary freight carrier, higher shipping costs or shipping delays could disrupt our supply chain and cause a decline in our net revenues or a reduction in our earnings.

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

If we fail to accurately predict our volume growth, hire too many or too few technicians, or manufacture too many or too few products, the delivery time for our products could be delayed or our costs may exceed our revenues, each of which could adversely affect our results of operations.

If we fail to accurately predict our volume growth, we may inaccurately estimate the staffing, materials or storage required to manufacture our products. If we underestimate volume growth, our growth may exceed our manufacturing capacity of one or more of our suppliers or manufacturing facilities, we may be understaffed and we may not have sufficient materials.

Specifically, our manufacturing process relies on sophisticated computer software and requires new technicians to undergo a relatively long training process, often 120 days or longer. As a result, if we are unable to accurately predict our volume growth, we may have an insufficient number of trained technicians to ensure products are manufactured and delivered within the time frames our customers expect. Without sufficient capacity, trained personnel or materials, we may be unable to provide our products to customers in a timely manner, which could damage our relationships with our existing customers or harm our ability to attract new customers. This could cause a decline in our net revenues and net income and could adversely affect our results of operations.

Conversely, if we over estimate our growth, we may have excess expenses caused by excess staffing, materials, and capacity. If we hire and train too many technicians in anticipation of volume growth that does not materialize, materializes at a rate slower than anticipated, or if volumes decline, our costs and expenditures may outpace our revenues or revenue growth, harming our gross margin and financial results. Additionally, in order to secure supplies for production of products, we sometimes enter into non-cancelable minimum purchase commitments with vendors, which could impact our ability to adjust our inventory to reflect declining market demands. If demand for our products is less than we expect, we may experience additional excess and obsolete inventories and be forced to incur additional charges and our profitability may suffer.

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

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

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

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

Our success depends in part on our proprietary technology, and if we fail to successfully obtain or enforce our intellectual property ("IP") rights, our competitive position may be harmed. Litigating claims of this type is costly and could distract our management and cause a decline in our results of operations and stock price.

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

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

We may not be afforded the protection of a patent if our currently pending or future patent filings do not result in the issuance of patents or we fail to apply for patent protection. We may fail to apply for a patent if our personnel fail to disclose or recognize new patentable ideas or innovations. Remote working can decrease the opportunities for our personnel to collaborate, thereby reducing the opportunities for effective invention disclosures and patent application filings. We may choose not to file a

foreign patent application if the limited protections provided by a foreign patent outweigh the costs to obtain it. Our foreign patent portfolio is less extensive than our U.S. portfolio.

We also rely on protection of our copyrights, trademarks, trade secrets, know-how and proprietary information. We generally enter into confidentiality agreements with our employees, consultants and collaborative partners upon commencement of a relationship with us; however, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist when unauthorized uses or disclosures occur.

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 adverse 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, interferences, oppositions, re-exams, *inter partes* reviews, post grant reviews or other proceedings have been necessary and will likely be needed in the future to determine the validity and scope of certain of our IP rights and the IP rights claimed by third parties 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. Asserting or defending these types of proceedings can be unpredictable, protracted, time consuming, expensive and distracting to management and technical personnel. The outcome of such proceedings could adversely affect the validity and scope of our patent or other IP rights, hinder our ability to manufacture and market our products, require us to seek a license for infringing products or technologies or result in the assessment of significant monetary damages. An unfavorable ruling could include monetary damages, an injunction prohibiting us from selling our products, or an exclusion order preventing us from importing our products in one or more countries. Moreover, independent actions by competitors, customers or others have been brought alleging that our efforts to assert or attempt to enforce our patent or other IP rights constitute unfair competition or violations of antitrust laws in the U.S. and other jurisdictions and investigations and additional litigation based on the same or similar claims may be brought in the future. The potential effects on our business operations resulting from litigation, whether or not ultimately determined in our favor or settled by us, are costly and could adversely affect our results of operations and stock price.

If we or any vendors on whose products or services we rely for our products and services infringe the patents or IP rights of other parties or are subject to a patent infringement claim, our ability to grow our business may be severely limited.

Extensive litigation over patents and other IP rights is common in the medical device, optical scanner, 3D printing and other technologies and industries on which our products and services are based. We have been sued for infringement of third parties' patents in the past and we are currently defending patent infringement lawsuits and other legal claims. In addition, we periodically receive letters from third parties drawing our attention to their patent rights. While we do not believe we infringe upon any valid and enforceable rights that have been brought to our attention, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of IP lawsuits, interference proceedings and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination in any legal proceeding to which we may become a party could subject us to significant liabilities, exclusion orders or injunctions that may prevent or limit our rights to sell or import our products in one or more countries. An adverse determination of this nature could require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected.

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

As a supplier of medical devices and solutions, 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:

- $\bullet \quad \text{the storage, transmission and disclosure of medical information and healthcare records;} \\$
- prohibitions against the offer, payment or receipt of remuneration to induce referrals to entities providing healthcare services or goods or to induce the order, purchase or recommendation of our products; and
- the marketing and advertising of our products.

The healthcare market itself is also highly regulated and subject to changing political, economic and regulatory influences. For instance, regulations affecting the security and privacy of patient healthcare information applicable to healthcare providers

and their business associates, such as HIPAA, may require us to make significant and unplanned enhancements of software applications or services, result in delays or cancellations of orders, or result in the revocation of endorsement of our products and services by healthcare participants. Our critical vendors and service providers are similarly subject to various regulations. Our failure or the failure of our suppliers, customers, advertisers and influencers to strictly adhere to clearances or approvals in the labeling, marketing and sales of our products and services could subject us to claims or litigation, including actions alleging false or misleading advertising, unfair or anti-competitive business practices or other violations of laws or regulations, which may result in costly investigations, fines, penalties, as well as material judgments, settlements or decrees. There can be no assurance that we will adequately address the business risks associated with the implementation and compliance with such laws or that we will be able to take advantage of any resulting business opportunities.

Furthermore, in general before we can sell a new medical device or market a new use of or claim for an existing product, we must obtain clearance or approval to gain market access unless an exemption applies. For instance, in the U.S., FDA regulations are wide ranging and govern, among other things:

- · product design, development, manufacturing and testing;
- product labeling;
- · product storage;
- pre-market clearance or approval;
- · complaint handling and corrective actions;
- · advertising and promotion; and
- · product sales and distribution.

It takes significant time, effort and expense to obtain and maintain FDA clearances or approvals of products and services and there is no guarantee we will successfully or timely obtain or maintain approvals in all or any of the countries in which we do business now or in the future. In other countries, the requirements to obtain and maintain similar approvals may differ materially from those of the FDA and may require additional time and expense. Moreover, these laws may change resulting in additional time and expense or loss of approvals. Additionally, the impact of the COVID-19 pandemic on normal governmental operations may delay our efforts to obtain and maintain approvals, possibly significantly. If approvals to market our products or services are delayed, whether in the U.S. or other countries, we may be unable to offer them in markets we deem important to our business. Failure or delays to obtain or maintain regulatory approvals may materially harm our domestic or international operations, and our business as a whole adversely impacted.

Any failure to comply with applicable regulatory requirements could result in enforcement actions in the U.S. and other countries. For example, enforcement actions by the FDA may include one or more of the following sanctions:

- · warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- · withdrawing clearance or pre-market approvals previously granted; and
- · criminal prosecution.

We and certain of our vendors must also comply with facility registration and product listing requirements of the FDA and adhere to applicable Quality System regulations. The FDA enforces its Quality System regulations through periodic unannounced inspections. Our failure to satisfactorily correct an adverse inspection finding or to comply with applicable manufacturing regulations could result in enforcement actions, and we may be required to find alternative manufacturers, which could be a long and costly process. Any enforcement action by the FDA or foreign governments could have a material adverse effect on us.

In addition, while we provide significant training to our personnel, they may not properly adhere to our policies or applicable laws or regulations. If our employees fail to comply with any or all laws or regulations or our policies or procedures, it could result in violations of laws or regulations and subject us to harm to our reputation, loss of customers, loss or revenues, or regulatory investigations and actions.

Consequently, if we cannot successfully obtain approval for our products or services or timely and cost-effectively maintain compliance with laws regulating our products and services, our results of operations and financial condition could be harmed.

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

We are highly dependent on our supply chain, particularly manufacturers of specialized scanning equipment, rapid prototyping machines, resin and other advanced materials, as well as the optics, electronic and other mechanical components of our intraoral scanners.

We maintain single supply relationships for many of these machines and materials. In particular, our CT scanning and stereolithography equipment used in our aligner manufacturing and many of the critical components for the optics of our scanners are provided by single suppliers. We rely on a single third-party manufacturer to supply key sub-assemblies for our iTero Element scanner. We purchase the vast majority of our resin and polymer, the primary raw materials used in our manufacturing process for clear aligners, from a single source. By using single suppliers for materials and manufacturing in a limited number of locations, we risk multiple supply chain vulnerabilities. For example, damage or destruction of a facility can materially disrupt our ability to timely deliver key components and materials or products or a supplier could encounter financial, operating or other difficulties, be unable to hire or maintain personnel, fail to timely obtain supplies, fail to maintain manufacturing standards or controls, or fail to timely deliver materials, parts or components. Any one of these occurrences would impact our supply chain.

Restrictions in response to the pandemic and other macroeconomic factors have affected and are expected to continue to affect our supply chain. The manufacture of product components, the final assembly of our products and other critical operations are concentrated in certain geographic locations, including China. A significant portion of our finished goods product distribution occurs through China and EMEA. Each of these areas has been affected by the pandemic and has implemented measures to try to contain its spread, including restrictions on manufacturing facilities, commerce, travel, our support operations and workforce, and our customers, strategic partners, vendors and suppliers. There is considerable uncertainty regarding the current and future impact of such measures, including reduced availability or increased cost of air transport, port closures and increased border controls and closures. Any or all restrictions can limit our manufacturers' capacity to produce our parts or products and have a material adverse effect on our supply chain.

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

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

We rely on highly skilled personnel and, if we fail to attract, motivate, train or retain highly skilled personnel, it may be more difficult to grow effectively and pursue our strategic priorities.

We are highly dependent on the talent and effort of highly skilled employees, including orthodontists and production technicians in our treatment planning facilities, and employees on our clinical engineering, technology development and sales teams. To be successful, we must effectively manage our growth through our ability to identify, hire, develop, motivate, train and retain these skilled employees as well as personnel throughout our organization.

We provide significant training to our personnel and our business will be impacted if our training fails to properly prepare our personnel to perform the work required, we are unable to successfully instill technical expertise in new and existing personnel or if our techniques prove unsuccessful or not cost-effective.

Moreover, for certain roles, this training and experience can make key personnel, such as our sales personnel, highly desirable by competitors and lead to increased attrition. The loss of the services and knowledge from our highly skilled employees may significantly delay or prevent the achievement of our development and business objectives and could harm our

business. For example, it can take up to twelve months or more to train sales representatives to successfully market and sell our products and for them to establish strong customer relationships.

For more discussion related to our personnel and corporate culture see the risk factor, "We rely on our personnel and, if we fail to attract, motivate or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities."

If we are unable to expand our workforce, including key sales and other skilled personnel, retain key personnel or quickly replace personnel with individuals of equivalent technical expertise and qualifications, our net revenues and our ability to maintain market share could be materially harmed.

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

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

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

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

Compliance with current or future environmental, social, and governance ("ESG") laws may materially increase our costs, expose us to potential liability and otherwise materially impact our business.

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

The environmental regulations related to greenhouse gases may have an impact on our or our suppliers' energy sources. Many U.S. and foreign regulators have enacted or are considering enacting new or additional limits on the emissions of greenhouse gases, including, but not limited to, carbon dioxide and methane, from power generation units using fossil fuels like

coal and natural gas. The effects of greenhouse gas emission limits on power generation that have been enacted already or that may be enacted in the future are subject to significant uncertainties, including the timing of any new requirements and levels of emissions reductions. Initiatives and legislation designed to reduce, restrict or eliminate greenhouse gas emissions from power generation may have the effect of increasing our costs and those of our suppliers and could result in manufacturing, transportation and supply chain disruptions and delays if clean energy alternatives are not readily available in adequate supply when required. Moreover, alternative energy sources that supply the power to meet our current and future demands as well as those of our suppliers and the global and regional economies in general, coupled with reduced investments in traditional energy sources and infrastructure, may fail to provide the predictable, reliable, and consistent energy that we, our suppliers and other businesses need for operations.

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

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

General Risk Factors

We rely on our personnel and, if we fail to attract, motivate or retain personnel, or if our growth harms our corporate culture, it may be more difficult to grow effectively and pursue our strategic priorities.

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

We are considering adjusting our remote working policies, which may cause our culture to change, cause us to incur additional costs, or cause us to lose talent or fail to attract talent. Many of our employees have worked remotely during the COVID-19 pandemic, which makes it difficult to maintain or enhance our culture, especially for new employees onboarded remotely. As we evaluate when and how to return employees to our offices globally, we continue to assess the impact various return-to-office plans may have on our culture, morale, and hiring and retention, particularly considering tight labor markets and generous or broad remote working policies being adopted by companies against whom we compete for talent. Should we choose to require employees to return to the office, implement or modify a remote working policy, and/or allow or modify a hybrid approach in which employees can continue to work from home or other remote locations on a limited or part time basis only, it may materially increase our costs or create unforeseen challenges or complications, including:

- difficulties maintaining our corporate culture, disruption of morale or decreased loyalty;
- negative impacts to collaboration, performance and productivity;
- increased employee stress, fatigue or "burn out" by employees unable to disengage their work life from the home life;
- increased operational, governance, compliance, and tax risks;
- increased attrition or limits to our ability to attract employees who prefer for convenience or for safety reasons to continue working remotely full time, or in offices or geographies different from where they were hired to work or are expected to work;
- problems managing office space requirements;

- concerns regarding favoritism or discrimination;
- · strains to our business continuity plans and difficulties achieving our strategic objectives; and
- increased labor and employment claims and litigation.

Furthermore, our compensation and benefit arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating existing employees. In addition, other internal and external factors can impact our ability to hire and retain talent, including insufficient advancement or career opportunities, restrictive immigration policy and regulatory changes, an increase in employees choosing to retire or quit with no immediate intentions to continue working and significantly higher demand for technical and digital talent.

If we are unable to attract and retain personnel that meet our selection criteria or relax our standards in order to meet the demands of our growth or if our growth is not managed effectively, our corporate culture, ability to achieve our strategic objectives, and our compliance with obligations under our internal controls and other requirements may be harmed.

Business disruptions could seriously harm our financial condition.

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

Human error can have a significant effect on our business. While we train our employees and perform our due diligence when contracting with third parties, mistakes and accidents still occur. For instance, in March 2021, a container ship carrying some of our products was stuck in the Suez Canal for six days. Although this did not have a material adverse effect on our business, there is no assurance that such incidents may not impact us in a material way in the future.

Natural disasters can impact our business, including as a result of earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, extreme weather conditions, power outages, restrictions and shortages, telecommunications failures, materials scarcity and price volatility, and medical epidemics or health pandemics. Climate change is likely to increase both the frequency and severity of natural disasters and, consequently, risks to our operations and growth. Our digital dental modeling and certain of our customer facing operations are primarily processed in our facilities located in Costa Rica. Our aligner molds and finished aligners are fabricated in Mexico and China. Our locations in Costa Rica and Mexico as well as others are in earthquake zones and may be subject to other natural disasters. Moreover, a significant portion of our research and development activities are located in California, which suffers from earthquakes, periodic droughts, power shortages and wildfires. If there is a major earthquake or any other natural disaster in a region where one of these facilities is located, our employees could be impacted, our research could be lost, and our ability to create ClinCheck treatment plans, respond to customer inquiries or manufacture and ship our aligners could be compromised which could result in our customers experiencing significant delays receiving their aligners and a decrease in service levels.

When human induced or natural disasters occur, they may, individually or in the aggregate, affect our ability to provide products, services and solutions to our customers, and could cause production delays or limitations, create adverse effects on distributors, disrupt supply chains, result in shipping and distribution disruptions and reduce the availability of or access to one or more facilities, any of which could materially and adversely affect our business, financial condition and results of operations.

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 policies. A change in these policies or in the way these policies are interpreted by us or regulators can have a significant effect on our reported results and may even retroactively affect previously reported transactions.

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 have an adverse effect on our stock price.

We are required to furnish in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting that includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether our internal control over financial reporting is effective. Our internal controls may become inadequate because of changes in personnel, updates and upgrades to existing software including our ERP software system, changes in accounting standards or interpretations of existing standards,

and, as a result, the degree of compliance of our internal control over financial reporting with the existing policies or procedures may become ineffective. Establishing, testing and maintaining an effective system of internal control over financial reporting requires significant resources and time commitments on the part of our management and our finance staff, may require additional staffing and infrastructure investments and increases our costs of doing business. If we are unable to assert that our internal control over financial reporting is effective in any future period (or if our auditors are unable to express an opinion on the effectiveness of our internal controls or conclude that our internal controls are ineffective), the timely filing of our financial reports could be delayed or we could be required to restate past reports, and cause us to lose investor confidence in the accuracy and completeness of our financial reports in the future, which could have an adverse effect on our stock price.

We are exposed to fluctuations in currency exchange rates and inflation, each of which could negatively affect our financial condition and results of operations.

Although the U.S. dollar is our reporting currency, a growing portion of our net revenues and net income are generated in foreign currencies. Net revenues and net income generated by subsidiaries operating outside of the U.S. are translated into U.S. dollars using constantly, often substantially, fluctuating exchange rates. As a result, negative movements in exchange rates against the U.S. dollar have and may increasingly adversely affect our net revenues and net income in our consolidated financial statements. We enter into currency forward contract transactions in an effort to cover some of our exposure to currency fluctuations, but there is no assurance these transactions will fully or effectively hedge our exposure to currency fluctuations, and, under certain circumstances, these transactions could have an adverse effect on our financial condition.

We also experienced rising inflationary pressures in 2021 and expect such pressures to continue in 2022. Cost inflation, including increases in ocean container rates, raw material prices, labor rates, and domestic transportation costs threaten to impact our profitability and our ability to recover these cost increases through price increases may continue to lag, resulting in downward pressure on our gross margin and operating margin. Any attempts to offset cost increases with price increases may result in reduced sales, increase customer dissatisfaction or otherwise harm our reputation.

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

The primary objective of our investment activities is to preserve principal. To achieve this objective, a majority of our marketable investments are investment grade, liquid, fixed-income securities and money market instruments denominated in U.S. dollars. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition. Moreover, the performance of certain securities in our investment portfolio correlates with the credit condition of the U.S. financial sector. In an unstable credit or economic environment, it is necessary to assess the value of our investments more frequently and we might incur significant realized, unrealized or impairment losses associated with these investments.

Additionally, in July 2017, the United Kingdom Financial Conduct Authority announced that it would stop compelling banks to submit interest rates for the calculation of the London Interbank Offered Rate ("LIBOR") after 2021. Although we do not have any outstanding debt under our 2020 Credit Facility, were we to draw on it, the outstanding amounts would bear interest at fluctuating interest rates on an approved replacement benchmark. We also have other contracts indexed to LIBOR. We continue to monitor this matter and evaluate the related risks and potential impact of LIBOR's expiration. Any indebtedness that we incur may be indexed to a replacement benchmark, such as the Secured Overnight Financing Rate ("SOFR"). Any such change could cause the effective interest rate under an agreement, including our 2020 Credit Facility, and our overall interest expense to increase, adversely affecting our cash flows and results of operations.

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

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

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

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in the global economic environment, changes in legal entity structure or activities performed within our entities, changes in tax laws, regulations and/or rates, new or changes to accounting pronouncements, changing interpretations of existing tax laws or regulations, changes in the relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, changes in overall levels of pretax earnings, the future levels of tax benefits of stock-based compensation, settlement of income tax audits and non-deductible goodwill impairments. For example, our effective tax rate varied significantly in the first quarter of fiscal 2020 due to the relocation of our EMEA regional headquarters from the Netherlands to Switzerland.

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

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

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

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

We are routinely subject to audits regarding our tax reporting and remissions by local and national governments. We may also be subject to audits in U.S. states, local and foreign jurisdictions for which we have not accrued tax liabilities. The positions we take and assumptions we make regarding taxes as well as the amounts we collect or remit may be challenged and we may be liable for failing to collect or remit all or any portion of taxes deemed owed or the taxes could exceed our estimates. If we dispute rulings or positions taken by tax authorities, we may incur expenses and expend significant time and effort to defend our positions, which may be costly.

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

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

Periodically, we may acquire, or make investments in, complementary companies, products or technologies like our acquisition of exocad in 2020. Alternatively, we may be unable to find suitable investment or acquisition targets in the future, and we may not be able to complete investments or acquisitions on favorable terms, if at all. If we do make investments or complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals or desired synergies, and any investments that we make or acquisitions we complete could be viewed negatively by our customers, securities analysts and investors. Moreover, to the extent we make strategic investments, the companies in which we invest may fail or we may ultimately own less than a majority of the outstanding shares of the company and be outvoted on critical matters or issues that could harm us or the value of our investment.

Additionally, as an organization we do not have a history of significant acquisitions or integrating their operations and cultures with our own. As such we are subject to multiple vulnerabilities and risks when making a strategic investment or acquisition, including we may:

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

Moreover, opposition to one of more acquisitions could lead to negative ratings by analysts or investors, give rise to objections by one or more stockholders or result in stockholder activism, any of which could harm our stock price. Acquisitions can also lead to large non-cash charges that can have an adverse effect on our results of operations as a result of write-offs for items such as future impairments of intangible assets and goodwill or the recording of stock-based compensation.

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

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

- the impact on global and regional economies as a result of the COVID-19 pandemic;
- quarterly variations in our results of operations and liquidity or changes in our forecasts and guidance;
- changes in recommendations by the investment community or speculation in the press or investment community regarding estimates of our net revenues, operating results or other performance indicators;
- announcements by us or our competitors or new market entrants, including strategic actions, management changes, and material transactions or acquisitions;
- technical factors in the public trading markets for our stock that may produce price movements that may or may not comport with macro, industry
 or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as it may be expressed on financial
 trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other
 derivatives on our common stock, fractional share trading, and other technical trading factors or strategies;
- announcements regarding stock repurchases, sales of our common stock, credit agreements and debt issuances;
- announcements of technological innovations, new, additional or revised programs, business models, products or product offerings by us, our customers or competitors;
- key decisions in pending litigation, new litigation, settlements, judgments or decrees;
- · sales of stock by us, our officers or directors; and
- · general economic market conditions.

In addition, the stock market in general, and the market for technology and medical device companies, in particular, have experienced extreme price and volume fluctuations that are often unrelated to or disproportionate to the operating performance of those companies. 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 federal funds rate in the U.S. and austerity measures of governments intended to control budget deficits. Historically, our stock has fluctuated materially based on broad

economic and industry factors unrelated to our actual performance and future changes in monetary policies, austerity, and other market factors may seriously harm the market price of our common stock, regardless of our operating performance. Historically, securities litigation, including securities class action lawsuits and securities derivative lawsuits, is often brought against an issuing company following periods of volatility in the market price of its securities and we have not been excepted from such litigation.

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

We have a history of recurring stock repurchase programs intended to return capital to our investors. Future stock repurchase programs are contingent on a variety of factors, including our financial condition, results of operations, business requirements, and our Board of Directors' continuing determination that stock repurchases are in the best interests of our stockholders and in compliance with all applicable laws and agreements. There is no assurance that we will continue repurchasing our common stock in the future, consistent with historical levels or at all, or that our stock repurchase programs will have a beneficial impact on our stock price.

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

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

Increased scrutiny of our ESG policies and practices have and will likely continue to result in additional costs and risks, and may adversely impact our reputation, employee retention, and willingness of customers and suppliers to do business with us.

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

	Item	1B.	Unresolved Stat	ff Comments.
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None.

Item 2. Properties.

We occupy several leased and owned facilities. As of December 31, 2021, the significant facilities occupied were as follows:

Location	Lease/Own	Primary Use
Tempe, Arizona, U.S.A.	Lease	Office for corporate headquarters
San Jose, California, U.S.A.	Own	Office for research & development and administrative personnel
Raleigh, North Carolina, U.S.A.	Own	Office for Americas regional headquarters
San Jose, Costa Rica	Lease and Own	Office for administrative personnel, treatment personnel, and customer care
Moscow, Russia	Lease	Office for research & development
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 significant facilities noted above are used mostly by all our reportable segments. We also own property in Wroclaw, Poland where we expect to open a new aligner fabrication facility that will begin serving doctors during the first half of 2022.

Item 3. Legal Proceedings.

For a discussion of legal proceedings, refer to Note 10 "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.

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

Market Information

Our common stock is traded on the NASDAQ Global Market under the symbol ALGN. As of February 21, 2022, there were approximately 53 holders of record of our common stock. Because the majority of our shares of outstanding common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

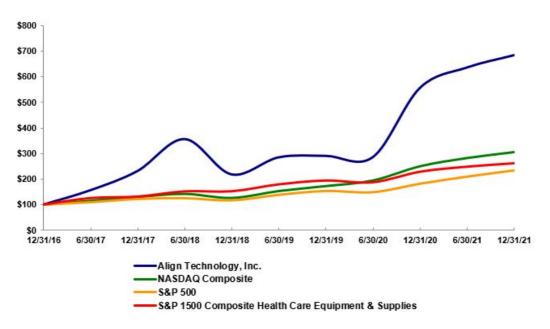
Performance Graph

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

The graph below matches our cumulative 5-year total stockholder return on common stock with the cumulative total returns of the NASDAQ Composite index, the S&P 500 index and the S&P 1500 Composite Health Care Equipment & Supplies index. The graph tracks the performance of a \$100 investment in our common stock and each index (with the reinvestment of all dividends) from December 31, 2016 to December 31, 2021.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

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



*\$100 invested on 12/31/16 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

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Unregistered Sales of Equity Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table summarizes the stock repurchase activity for the three months ended December 31, 2021:

Period	Total Number of Shares Repurchased	Average Price aid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Repurchased Under the Programs ⁽¹⁾
October 1, 2021 through October 31, 2021	_	\$ _	_	\$ 824,962,500
November 1, 2021 through November 30, 2021	150,031	\$ 666.53	150,031	\$ 724,962,500
December 1, 2021 through December 31, 2021	_	\$ _	_	\$ 724,962,500
Total	150,031		150,031	

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

Item 6. [Reserved]

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

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

A discussion regarding our financial condition and results of operations for fiscal 2021 compared to fiscal 2020 is presented under Results of Operations of this Form 10-K. Discussions regarding our financial condition and results of operations for fiscal 2020 compared to 2019 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, 2020, filed with the SEC on February 26, 2021, which is available without charge on the SEC's website at www.sec.gov and on our investor relations website at investor.aligntech.com.

Executive Overview of Results

Trends and Uncertainties

Our business strategic priorities remain focused on four principal pillars of growth: (i) international expansion; (ii) GP adoption; (iii) patient demand and conversion; and (iv) orthodontic utilization.

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

- Our growth depends on the continued penetration and adoption of Invisalign products, intraoral scanners and CAD/CAM solutions in international
 markets. We continue to invest in manufacturing operations, research and development, clinical treatment planning, sales and marketing and
 building our quality and regulatory capabilities in existing and emerging markets globally. For instance, in 2021, we:
 - opened new offices in Israel to support the long-term growth of iTero scanner and services business for treatment planning and other operations;
 - announced plans to open an aligner fabrication facility in Wroclaw, Poland as a part of our strategy to bring operational facilities closer to
 customers and thereby serve them more quickly and respond to their needs more effectively as well as new treatment planning operations
 in targeted regional geographies; and

- expanded our sales and marketing efforts into new countries and regions, including establishing offices in the African countries of Ghana and Morocco
- We continue to see growth opportunities with international orthodontists and GP customers, particularly with adopters of digital dentistry platforms as we continue to tailor our sales and marketing strategies 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, 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 of these regions.
- We believe our training and education efforts are important to building the confidence within the GP and orthodontic communities needed to
 increase their adoption and utilization of clear aligner treatment. Accordingly, we continue to expand our Invisalign customer base by educating
 new doctors on the benefits of digital dentistry through the Invisalign system and demonstrating to GPs and orthodontists how the iTero portfolio
 of intraoral scanners and CAD/CAM restorative services and workflows can increase the profitability of their dental practices by enhancing
 patient experiences.

However, training and education alone are insufficient to drive adoption and utilization growth sufficiently. We need to continue to innovate, develop and bring to market products and solutions that deliver the ever-increasing clinical precision and predictability doctors expect with the speed and convenience their patients require. For this reason, we expect to continue to invest in research and development and open facilities closer to our customers and their patients to timely and conveniently support them.

• Patient demand and conversion depends on making targeted investments in advertising and public relations through social media, influencers and other forms of digital communications to encourage patients to seek treatment from Invisalign trained doctors. We believe that well-designed, targeted sales and marketing promotions that build on our strong brand awareness and allow us to differentiate our products and solutions from traditional and emerging competitors. Accordingly, we continue to increase investments intended to grow consumer demand. For instance, in 2021, we introduced the "Invis-is" consumer advertising campaign with new creative content and influencers focused on teens, moms and young adults. We expect to make further investments to create additional demand for Invisalign system treatment driving more consumers to dental professionals for those treatments.

In addition, we are pursuing new lines of Consumer Products that are complementary to our doctor-prescribed principal products currently available in certain e-commerce channels in the U.S. Similarly, in order to grow our retainer business, which is significantly underpenetrated, we have begun investing more directly in marketing strategies focused on driving adoption and increasing market share in the U.S.

- We expect global orthodontic utilization rates to continue increasing overall 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 in office visits and less invasive and quicker treatments rise. In addition, the teenage and younger market makes up 75% of the approximately 21 million total annual global orthodontic case starts each year. As we continue to emphasize the benefits of the Invisalign system for teenage and younger patient treatments through education, training and sales and marketing programs, we expect utilization rates to rise. However, our utilization rates will fluctuate from period to period due to a variety of factors, which may include seasonal trends in our business, office closures or slowdowns related to COVID-19-related preventative measures and adoption rates for new products and features. Refer to "COVID-19 Pandemic Update" below for further details.
- To achieve these strategic pillars, we expect to continue hiring skilled employees in our clinical engineering, technology development, manufacturing, sales and management teams. Expanding our workforce will require that we offer competitive compensation and result in increasing costs which we expect to offset with increasing revenues.

COVID-19 Pandemic Update

The COVID-19 pandemic continues to cause significant volatility and uncertainty in the global and regional economies, leading to changes in consumer and business behavior, fear and market fluctuations, materials and product shortages and restrictions on business and individual activities, all of which is materially impacting supply and demand in broad sectors of the world markets. During 2021, many businesses and countries, including the U.S., continued imposing preventative and precautionary measures to mitigate the spread of the virus and its variants. As a result of the restrictive measures imposed, the

demand for digital solutions has increased. Society and businesses continue to adapt to practices such as social distancing and remote working that further the need for greater flexibility and convenience of digital solutions. Our efforts to promote the digital transformation of dental practices with our clear aligners, intraoral scanners, clinical treatment planning and other offerings has allowed us to quickly respond to fluctuating demands in the dental field in various regions.

Consequently, despite the economic challenges caused by the pandemic, our revenue grew by 59.9% in 2021 compared to 2020. The growth was a combination of non-COVID related increases as well as lower revenues in 2020 as the initial preventative measures to combat the spread of the virus resulted in significant office closures and materially reduced operating capacities for many of our customers. Our overall business performance has been strong, and we believe the digital transition to dentistry that began before the pandemic will continue to be positive for our business, results of operations, cash flows, and financial condition, although we intend to adjust spending to coincide with the fluctuating pace of recovery and changes in demand. As such, our recent operating results and levels of growth may not be indicative of our future performance.

The continuing evolution of the pandemic remains highly fluid and unpredictable, including the setbacks occurring as a result of new virus strains and new or additional operating restrictions imposed on businesses, supply chain shortages and delays, the positive impacts of vaccinations, the uncertainties regarding consumer spending as demand for entertainment, dining, and travel returns and remote working diminishes. Our top priority continues to be the health and safety of our employees and their families, our customers and their staff. In addition, new variants of the virus have caused unpredictable fluctuations in the number of patients seeking treatment and the number of doctors providing the services and treatments. These fluctuations have adversely impacted our results of operations from time to time in the recent past and are expected to continue to impact our results, particularly in the near term.

We continue to follow recommended safety measures, including encouraging employees to work from home when possible, suspending non-essential work travel, and implementing various access controls at our facilities. In order to overcome the supply chain shortages and delays, we are also proactively communicating with our suppliers and distributors and modifying our purchase order commitments to mitigate the risks of supply chain interruptions and maintaining inventory levels greater than historically required.

Further discussion of the impact of the COVID-19 pandemic on our business may be found in Part I, Item 1A of this Annual Report on Form 10-K under the heading "Risk Factors."

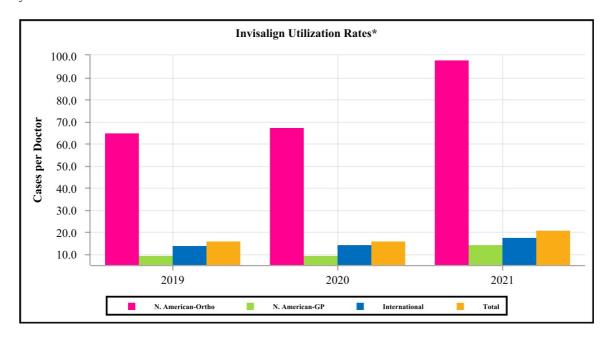
Key financial and operating metrics

We measure our performance against these strategic priorities by the achievement of key financial and operating metrics. For the year ended December 31, 2021, we achieved the following, taking into consideration that percentage changes from prior year financial results include the impact of COVID-19 and do not necessarily reflect our future growth rates:

- Revenues of \$3,952.6 million, an increase of 59.9% year-over-year;
- Clear Aligner revenues of \$3,247.1 million, an increase of 54.5% year-over-year reflecting the expanding opportunity for Invisalign system treatment among adults globally, as well as the underlying orthodontic market as we continue to build awareness of the Invisalign brand and drive utilization among teens and younger patients through increased consumer marketing.
 - Americas Clear Aligner revenues of \$1,544.8 million, an increase of 52.9% year-over-year;
 - International Clear Aligner revenues of \$1,498.7 million, an increase of 55.2% year-over-year;
 - Clear Aligner volume increase of 54.8% year-over-year and Clear Aligner volume increase for teenage patients of 47.3% year-over-year;
- Imaging Systems and CAD/CAM Services revenues of \$705.5 million, an increase of 90.4% year-over-year reflecting strong growth
 across all regions with continued adoption of the iTero Element 5D and 5D Plus Series of next generation scanners and imaging systems
 launched in February 2021, as well as increased average selling prices ("ASP") predominately due to favorable product mix shift towards
 higher priced scanners;
- Income from operations of \$976.4 million and operating margin of 24.7%;
- Effective tax rate of 23.7%;
- Net income of \$772.0 million with diluted net income per share of \$9.69;
- Cash, cash equivalents and marketable securities of \$1,296.7 million as of December 31, 2021;
- Operating cash flow of \$1,172.5 million;
- Capital expenditures of \$401.1 million, predominantly related to increases in our manufacturing capacity and facilities; and
- Number of employees was 22,540 as of December 31, 2021, an increase of 24.7% year-over-year.

Other Statistical Data and Trends

- Our primary goal is to establish clear aligners as the principal solution for the treatment of malocclusions and our Invisalign system as the treatment solution of choice by orthodontists, GPs and patients globally, our intraoral scanning platform as the preferred scanning protocol for digital dental scans, and our exocad CAD/CAM software as the solution of choice for dental labs. As of December 31, 2021, over 12 million people worldwide have been treated with our Invisalign system, over 68,000 iTero scanners have been sold and over 47,000 exocad software licenses have been installed. Management measures these results by comparing to the estimated 500 million people who can benefit from straighter teeth, 21 million annual orthodontic case starts and 2 million dental practices that could use intraoral scanners 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, dental professionals and/or labs and service providers to use iTero intraoral scanners, and dental labs and practitioners to install exocad CAD/CAM software.
- For the fourth quarter of 2021, total Invisalign cases submitted with a digital scanner in the Americas increased to 89.1%, up from 84.0% in the fourth quarter of 2020 and international scans increased to 80.8%, up from 73.7% in the fourth quarter of 2020. For the fourth quarter of 2021, 96.4% of Invisalign cases submitted by North American orthodontists were submitted digitally. Our annual utilization rates for the last three fiscal years are as follows:



*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 EMEA, APAC. Latin America ("LATAM") is excluded from the International region based on its immateriality to the year, however is included in the Total utilization.

- Total utilization rate in 2021 increased to 20.8 cases per doctor compared to 16.1 cases per doctor in 2020 and 15.9 cases per doctor in 2019.
 - *North America*: Utilization rate among our North American orthodontist customers increased to 98.1 cases per doctor in 2021 compared to 67.3 cases per doctor in 2020 and 65.0 cases per doctor in 2019 and the utilization rate among our North American GP customers increased to 14.3 cases per doctor in 2021 compared to 9.6 cases per doctor in 2020 and 9.5 cases per doctor in 2019.
 - *International:* International doctor utilization rate increased to 17.5 cases per doctor in 2021 compared to 14.5 cases per doctor in 2020 and 13.8 cases per doctor in 2019.

Results of Operations

Net Revenues by Reportable Segment

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

- · Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
 - · Comprehensive Products include, but are not limited to, Invisalign Comprehensive and Invisalign First.
 - Non-Comprehensive Products include, but are not limited to, Invisalign Moderate, Lite and Express packages and Invisalign Go and Invisalign Go Plus.
 - Non-Case products include, but are not limited to, retention products, Invisalign training, adjusting tools used by dental professionals
 during the course of treatment and, more recently, Consumer Products that are complementary to our doctor-prescribed principal products
 such as aligner cases (clamshells), teeth whitening products, cleaning solutions (crystals, foam and other material) and other oral health
 products available in certain e-commerce channels in the U.S.
- Our Systems and Services segment consists of our iTero intraoral scanning systems, which includes a single hardware platform and restorative or
 orthodontic software options. Our services include subscription software, disposables, rentals, 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, 2021, 2020 and 2019 are as follows (in millions):

		Year Ended	Decen	nber 31,	Year Ended December 31,											
Net Revenues	2021			2020		Cha	ınge			2020		2019		Change		
Clear Aligner revenues:																
Americas	\$	1,544.8	\$	1,010.2	\$	534.5	52.9	%	\$	1,010.2	\$	1,022.1	\$	(11.9)	(1.2)%	%
International		1,498.7		965.4		533.2	55.2	%		965.4		881.4		84.1	9.5 %	%
Non-case		203.7		125.8		77.8	61.9	%		125.8		122.3		3.5	2.9 %	%
Total Clear Aligner net revenues	\$	3,247.1	\$	2,101.5	\$	1,145.6	54.5	%	\$	2,101.5	\$	2,025.8	\$	75.7	3.7 %	%
Systems and Services net revenues		705.5		370.5		335.0	90.4	%		370.5		381.0		(10.6)	(2.8)%	%
Total net revenues	\$	3,952.6	\$	2,471.9	\$	1,480.6	59.9	%	\$	2,471.9	\$	2,406.8	\$	65.1	2.7 %	%
Systems and Services net revenues	\$	705.5	\$	370.5	\$	335.0	90.4	%		370.5	\$	381.0	\$	(10.6)	(2.8)%	%

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, 2021, 2020 and 2019 is as follows (in thousands):

	Year Ended Dec	ember 31,			Year Ended De	cember 31,		
	2021	2020	Char	ıge	2020	2019	Chang	ge
Total case volume	2,547.7	1,645.3	902.4	54.8 %	1,645.3	1,537.1	108.3	7.0 %

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

Total net revenues increased by \$1,480.6 million in 2021 as compared to 2020 primarily as a result of increases in Clear Aligner volume of 54.8% and an increase in the number of scanners recognized across most regions.

Clear Aligner - Americas

Americas net revenues increased by \$534.5 million in 2021 as compared to 2020 primarily due to a 57.6% increase in volume which resulted in higher net revenues of \$582.1 million, partially offset by lower ASP that decreased net revenues by

\$47.7 million. Lower ASP was mostly due to higher promotional discounts which decreased revenue by \$52.1 million and net deferrals which decreased revenues by \$40.3 million. The decreases in ASP were partially offset by favorable product mix shift which increased net revenues by \$34.2 million and favorable exchanges rates which increased net revenues by \$12.2 million.

Clear Aligner - International

International net revenues increased by \$533.2 million in 2021 as compared to 2020 primarily due to a 51.6% increase in volume which resulted in higher net revenues by \$497.8 million. Higher ASP increased net revenues by \$35.4 million mostly due to favorable exchange rates which increased net revenues by \$61.8 million and favorable product mix shift which increased net revenues by \$27.6 million. The increases in ASP were partially offset by higher net deferrals which decreased net revenues by \$49.6 million.

Clear Aligner - Non-Case

Non-case net revenues increased by \$77.8 million in 2021 compared to 2020 due to increased volume for retention products across all regions primarily driven by Vivera retainers.

Systems and Services

Systems and Services net revenues increased by \$335.0 million in 2021 as compared to 2020 due to a higher number of scanners recognized which increased net revenues by \$186.3 million. Net revenues also increased by \$97.7 million as a result of higher iTero service revenues mostly due to a larger scanner install base and additional exocad CAD/CAM revenues. Additionally, higher scanner ASP increased net revenues by \$51.0 million mostly due to favorable product mix shift towards higher priced scanners such as the iTero Element Plus Series.

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

	Year Ended	Decen	nber 31,		Year Ended			
	2021		2020	Change	2020	2019		Change
Clear Aligner								
Cost of net revenues	\$ 772.7	\$	569.3	\$ 203.4	\$ 569.3	\$ 526.0	\$	43.3
% of net segment revenues	23.8 %		27.1 %		27.1 %	26.0 %	6	
Gross profit	\$ 2,474.4	\$	1,532.1	\$ 942.2	\$ 1,532.1	\$ 1,499.7	\$	32.4
Gross margin %	76.2 %		<i>7</i> 2.9 %		<i>7</i> 2.9 %	74.0 %	6	
Systems and Services								
Cost of net revenues	\$ 244.5	\$	139.4	\$ 105.1	\$ 139.4	\$ 136.9	\$	2.5
% of net segment revenues	34.7 %		37.6 %		37.6 %	35.9 %	6	
Gross profit	\$ 461.0	\$	231.1	\$ 229.9	\$ 231.1	\$ 244.2	\$	(13.1)
Gross margin %	65.3 %		62.4 %		62.4 %	64.1 %	6	
Total cost of net revenues	\$ 1,017.2	\$	708.7	\$ 308.5	\$ 708.7	\$ 662.9	\$	45.8
% of net revenues	25.7 %		28.7 %		28.7 %	27.5 %	6	
Gross profit	\$ 2,935.4	\$	1,763.2	\$ 1,172.1	\$ 1,763.2	\$ 1,743.9	\$	19.3
Gross margin %	74.3 %		71.3 %		71.3 %	<i>7</i> 2.5 %	6	

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

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

Clear Aligner

The gross margin percentage increased in 2021 as compared to 2020 primarily due to manufacturing efficiencies driven by higher production volumes.

Systems and Services

The gross margin percentage increased in 2021 as compared to 2020 as a result of higher ASP from a product mix shift and an increase in service revenues which was partially offset by higher freight costs.

Selling, general and administrative (in millions):

	Year Ended	Decer	nber 31,	Year Ended December 31,								
	 2021		2020	,	Change		2020		2019		Change	
Selling, general and administrative	\$ 1,708.6	\$	1,200.8	\$	507.9	\$	1,200.8	\$	1,072.1	\$	128.7	
% of net revenues	43.2 %		48.6 %				48.6 %		44.5 %	,)		

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, public relations, 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 2021 compared to 2020 primarily due to higher compensation related costs of \$235.0 million from higher salaries, fringe benefits, incentive bonuses and commissions due to increased headcount as we continue to invest in sales and marketing to penetrate into new markets as well as higher advertising and marketing costs of \$183.4 million.

Research and development (in millions):

		Year Ended	Decen	nber 31,			Year Ended	Decen	ıber 31,		
	<u></u>	2021		2020	_	Change	2020		2019	_'	Change
Research and development	\$	250.3	\$	175.3	\$	75.0	\$ 175.3	\$	157.4	\$	17.9
% of net revenues		6.3 %)	7.1 %			7.1 %		6.5 %		

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 2021 compared to 2020 primarily due to higher compensation costs including higher salaries, fringe benefits and incentive bonuses mainly from increased headcount as we continue to focus our investments in innovation and research.

Income from operations (in millions):

	Year Ended	Decen	nber 31,		Year Ended		
	 2021		2020	Change	2020	2019	Change
Clear Aligner			_	_			
Income from operations	\$ 1,325.9	\$	768.0	\$ 557.8	\$ 768.0	\$ 836.0	\$ (67.9)
Operating margin %	40.8 %		36.5 %		36.5 %	41.3 %	
Systems and Services							
Income from operations	\$ 259.1	\$	96.1	\$ 163.1	\$ 96.1	\$ 137.7	\$ (41.7)
Operating margin %	36.7 %		25.9 %		25.9 %	36.1 %	
Total income from operations 1	\$ 976.4	\$	387.2	\$ 589.2	\$ 387.2	\$ 542.5	\$ (155.3)
Operating margin %	24.7 %		15.7 %		15.7 %	22.5 %	

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

Refer to Note 18 "Segments and Geographical Information" of the Notes to Consolidated Financial Statements for details on unallocated corporate expenses and the reconciliation to Consolidated Income from Operations.

Clear Aligner

Operating margin percentage increased in 2021 compared to 2020 due to higher gross margins and operating leverage on higher net revenues.

Systems and Services

Operating margin percentage increased in 2021 compared to 2020 due to operating leverage on higher net revenues and higher gross margins due to a favorable mix shift towards higher priced scanners.

Interest income (in millions):

	Year Ended I	Decem	ber 31,	Year Ended December 31,								
	2021		2020		Change		2020		2019		Change	
Interest income	\$ 3.1	\$	3.1	\$		\$	3.1	\$	12.5	\$	(9.4)	
% of net revenues	0.1 %		0.1 %				0.1 %		0.5 %			

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. In 2021, there was no change to interest income compared to 2020.

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

	Year Ended	Decen	ıber 31,	Year Ended December 31,								
	2021		2020		Change		2020		2019		Change	
Other income (expense), net	\$ 32.9	\$	(11.3)	\$	44.3	\$	(11.3)	\$	7.7	\$	(19.0)	
% of net revenues	0.8 %		(0.5)%				(0.5)%		0.3 %			

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 2021 compared to 2020 primarily due to a \$43.4 million gain related to the SDC arbitration award recognized in the first quarter of 2021, a \$10.2 million loss on a foreign currency forward contract related to the exocad acquisition recognized in 2020 and an increase due to fair value changes relating to our investments in privately held companies recognized during 2021 compared to 2020. These increases were partially offset by net foreign exchange losses in 2021 as compared to net foreign exchange gains in 2020.

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

	Year Ended	Decei	nber 31,		Year Ended	Decem	ber 31,		
	2021		2020	Change	2020		2019		Change
Provision for (benefit from) income taxes	\$ 240.4	\$	(1,396.9)	\$ 1,637.3	\$ (1,396.9)	\$	112.3	\$	(1,509.3)
Effective tax rates	23.7 %		(368.6)%		(368.6)%		20.0 %	ó	

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, 2021 compared to 2020 is primarily attributable to the recognition of tax benefits associated with the intra-entity transfer of certain intellectual property rights and fixed assets during the year ended December 31, 2020.

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

profitability of our Swiss headquarters and the recognition of this tax benefit is allowed for a maximum recovery period of 15 years.

Liquidity and Capital Resources

Liquidity and Trends

As of December 31, 2021 and 2020, we had the following cash and cash equivalents and short-term and long-term marketable securities (in thousands):

	December 31,					
		2021		2020		
Cash and cash equivalents	\$	1,099,370	\$	960,843		
Marketable securities, short-term		71,972		_		
Marketable securities, long-term		125,320		_		
Total	\$	1,296,662	\$	960,843		

As of December 31, 2021 and 2020, approximately \$713.8 million and \$412.5 million, respectively, of cash, cash equivalents and marketable securities was held by our foreign subsidiaries. Our intent is to permanently reinvest our earnings from our international operations going forward, and our current plans do not require us to repatriate them to fund our U.S. operations as we generate sufficient domestic operating cash flow and have access to external funding under our \$300.0 million revolving line of credit. We believe that our current cash balances and the borrowing capacity under our credit facility, if necessary, will be sufficient to fund our business for at least the next 12 months.

Our material cash requirements as of December 31, 2021 are as below:

- Our purchase commitments for goods and services, excluding capital expenditures, totaled \$1,278.0 million, of which \$731.0 million will be payable within the next 12 months. These commitments primarily relate to agreements with contract manufacturers and suppliers, sales and marketing services, research and development services and technological services.
- We expect our investments in capital expenditures to exceed \$350.0 million for the next 12 months. Capital expenditures primarily relate to building construction and improvements as well as additional manufacturing capacity to support our international expansion. This includes our planned investment in an aligner fabrication facility in Wroclaw, Poland, which is expected to begin serving doctors in 2022, as a part of our strategy to bring operational facilities closer to customers. As we continue growing, we intend to expand our investments in research and development, manufacturing, treatment planning, sales and marketing operations to meet local and regional demand.
- We have future operating lease payments of \$160.8 million, which includes \$17.8 million for leases that have not yet commenced as of December 31, 2021. Refer to *Note 4* "*Leases*" of the *Notes to Consolidated Financial Statements* for details on the lease payments.
- We have \$725.0 million available for repurchase under the stock repurchase program authorized by our Board of Directors in May 2021. 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 13 "Common Stock Repurchase Programs" of the Notes to Consolidated Financial Statements* for details on our stock repurchase programs. Subsequent to year end, during February 2022, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of \$522.35 per share, including commissions, for an aggregate purchase price of \$75.0 million.

The following table summarizes our Consolidated Statements of Cash Flows for the year ended December 31, 2021, 2020 and 2019 (in thousands):

	fear Ended December 31,							
		2021		2020		2019		
Net cash provided by (used in):								
Operating activities	\$	1,172,544	\$	662,174	\$	747,270		
Investing activities		(563,430)		(231,506)		(350,444)		
Financing activities		(458,332)		(30,808)		(485,540)		
Effects of foreign exchange rate changes on cash, cash equivalents, and restricted cash		(12,117)		10,480		2,282		
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$	138,665	\$	410,340	\$	(86,432)		

Operating Activities

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

Significant adjustments to net income

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

Significant changes in working capital

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

For the year ended December 31, 2020, cash flows from operations of \$662.2 million resulted primarily from our net income of approximately \$1,775.9 million as well as the following:

Significant adjustments to net income

- Deferred taxes of \$1,491.6 million related to the one-time tax benefit associated with the intra-entity sale of certain intellectual property rights;
- · Stock-based compensation of \$98.4 million related to equity awards granted to employees and directors; and
- Depreciation and amortization of \$93.5 million related to our investments in property, plant and equipment and intangible assets.

Significant changes in working capital

- Increase of \$228.1 million in deferred revenues primarily related to increased case volumes in our Clear Aligner segment and timing of revenue recognition;
- · Increase of \$139.8 million in accounts receivable which is primarily a result of the increase and timing in our sales; and
- Increase of \$52.2 million in accounts payable due to timing of certain invoice payments.

Investing Activities

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

Net cash used in investing activities was \$231.5 million for the year ended December 31, 2020, which primarily consisted of cash paid for the acquisition of exocad of \$420.8 million, net of cash acquired and purchases of property, plant and equipment of \$154.9 million. These outflows were partially offset by maturities and sales of marketable securities of \$321.5 million and \$26.9 million received from payments on an unsecured promissory note issued by SDC in exchange for tendering our shares to them.

Financing Activities

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

Net cash used in financing activities was \$30.8 million for the year ended December 31, 2020 consisted of payroll taxes paid for equity awards through share withholdings of \$51.1 million which was partially offset by \$20.3 million of proceeds from the issuance of common stock.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

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

Determining the standalone selling price ("SSP"), allocation of consideration from the contract to the individual performance obligations and the appropriate timing of revenue recognition is the result of significant qualitative and quantitative judgments. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenues recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on our financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

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

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

Unfulfilled Performance Obligations for Clear Aligners and Scanners

The estimated revenues expected to be recognized in the future related to our unfulfilled performance obligations, including deferred revenues and backlog, as of December 31, 2021 is \$1,307.3 million. This estimate includes both product and service unfulfilled performance obligations and the time range reflects our best estimate of when we will transfer control to the customer and may change based on customer usage patterns, timing of shipments, readiness of customers' facilities for installation, and manufacturing availability all of which involve significant judgement. Generally, our deferred revenue will be recognized over a period of one to five years.

Goodwill and Finite-Lived Acquired Intangible Assets

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

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

If we were to have impairments to goodwill or finite-lived acquired intangible assets, it could adversely affect our operating results. During the fiscal year 2021 and 2020, we did not have any impairment charges related to our goodwill or acquired intangible assets.

Accounting for Income Taxes

We are subject to income taxes in the U.S. and numerous foreign jurisdictions. The evaluation of our uncertain tax positions involves significant judgment in the interpretation and application of U.S. GAAP and complex domestic and international tax laws related to the allocation of international taxation rights between countries. We are also required to evaluate the realizability of our deferred tax assets on an ongoing basis in accordance with U.S. GAAP, which requires the assessment of both of our historical and future performance as well as other relevant factors. Realization of our deferred tax assets is dependent on our ability to generate future taxable income which is determined based on assumptions such as estimated growth rates in revenues, gross margins, future cash flows and discount rates. The accuracy of these estimates could be affected by unforeseen events or actual results, and the sustainability of our future tax benefits is dependent upon the acceptance of these valuation estimates and assumptions by the taxing authorities.

Accounting for Legal Proceedings and Litigation

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

Recent Accounting Pronouncements

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

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

In the normal course of business, we are exposed to foreign currency exchange rate and interest rate 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 the COVID-19 pandemic. Further discussion of the impact of the COVID-19 pandemic on our business may be found in *Item 1A* of this Annual Report on Form 10-K under the heading "*Risk Factors*".

Interest Rate Risk

Changes in interest rates could impact our anticipated interest income on our cash equivalents and investments in marketable securities. Our investments are fixed-rate short-term and long-term securities. Fixed-rate securities may have their fair market value adversely impacted due to a rise in interest rates, and, as a result, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. As of December 31, 2021, we had approximately \$197.3 million invested in available-for-sale marketable securities. An immediate 10% change in interest rates would not have a material adverse impact on our future operating results and cash flows.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. Based on interest bearing liabilities we have as of December 31, 2021, we are not subject to risks from immediate interest rate increases.

Currency Rate Risk

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

We primarily enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on cash and certain trade and intercompany receivables and payables. These forward contracts are not designated as hedging instruments and do not subject us to material balance sheet risk due to fluctuations in foreign currency exchange rates. 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. These instruments are marked to market through earnings every period and generally are one month in original maturity. We do not enter into foreign currency forward contracts for trading or speculative purposes. As our international operations grow, we will continue to reassess our approach to managing the risks relating to fluctuations in currency rates. It is difficult to predict the impact forward contracts could have on our results of operations.

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

${\bf Item~8.~~Financial~Statements~and~Supplementary~Data.}$

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REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Align;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of Align are being made only in accordance with authorizations of management and directors of Align; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of Align's assets that could have a material effect on the financial statements.

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

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. 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, 2021, 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, 2021 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

/s/ JOSEPH M. HOGAN

Joseph M. Hogan President and Chief Executive Officer February 25, 2022

/s/ JOHN F. MORICI

John F. Morici Chief Financial Officer and Executive Vice President, Global Finance February 25, 2022

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, 2021 and 2020, and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, including the related notes and financial statement schedule listed in the index appearing under Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 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, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

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

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

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting, 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 18 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, 2021. 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. Determining the standalone selling price, allocation of consideration from the contract to the individual performance obligations, and the appropriate timing of revenue recognition is the result of significant qualitative and quantitative judgments. 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. Management also considers usage rates, which is the number of times a customer is expected to order additional aligners. Management's process for estimating usage rates requires significant judgment and evaluation of inputs, including historical usage data by region, country and channel.

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

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

/s/ PricewaterhouseCoopers LLP San Jose, California February 25, 2022

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,							
		2021		2020		2019		
Net revenues	\$	3,952,584	\$	2,471,941	\$	2,406,796		
Cost of net revenues		1,017,229		708,706		662,899		
Gross profit		2,935,355		1,763,235		1,743,897		
Operating expenses:								
Selling, general and administrative		1,708,640		1,200,757		1,072,053		
Research and development		250,315		175,307		157,361		
Impairments and other charges (gains), net		_		_		22,990		
Litigation settlement gain		_		_		(51,000)		
Total operating expenses		1,958,955		1,376,064		1,201,404		
Income from operations		976,400		387,171		542,493		
Interest income and other income (expense), net:								
Interest income		3,103		3,125		12,482		
Other income (expense), net		32,920		(11,347)		7,676		
Total interest income and other income (expense), net		36,023		(8,222)		20,158		
Net income before provision for (benefit from) income taxes and equity in losses of investee	'	1,012,423		378,949		562,651		
Provision for (benefit from) income taxes		240,403		(1,396,939)		112,347		
Equity in losses of investee, net of tax		_				7,528		
Net income	\$	772,020	\$	1,775,888	\$	442,776		
Net income per share:								
Basic	\$	9.78	\$	22.55	\$	5.57		
Diluted	\$	9.69	\$	22.41	\$	5.53		
Shares used in computing net income per share:								
Basic		78,917		78,760		79,424		
Diluted		79,670		79,230		80,100		

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,							
2021		2020		2019			
\$ 772,020	\$	1,775,888	\$	442,776			
(38,680)		44,383		1,787			
(495)		(194)		299			
(39,175)		44,189		2,086			
\$ 732,845	\$	1,820,077	\$	444,862			
\$	\$ 772,020 (38,680) (495) (39,175)	\$ 772,020 \$ (38,680) (495) (39,175)	2021 2020 \$ 772,020 \$ 1,775,888 (38,680) 44,383 (495) (194) (39,175) 44,189	2021 2020 \$ 772,020 \$ 1,775,888 (38,680) 44,383 (495) (194) (39,175) 44,189			

 $\label{thm:companying} \textit{ notes are an integral part of these consolidated financial statements.}$

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,				
		2021		2020	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	1,099,370	\$	960,843	
Marketable securities, short-term		71,972		_	
Accounts receivable, net of allowance for doubtful accounts of \$9,245 and \$10,239, respectively		897,198		657,704	
Inventories		230,230		139,237	
Prepaid expenses and other current assets		195,305		91,754	
Total current assets		2,494,075		1,849,538	
Marketable securities, long-term		125,320		_	
Property, plant and equipment, net		1,081,926		734,721	
Operating lease right-of-use assets, net		121,257		82,553	
Goodwill		418,547		444,817	
Intangible assets, net		109,709		130,072	
Deferred tax assets		1,533,767		1,552,831	
Other assets		57,509		35,151	
Total assets	\$	5,942,110	\$	4,829,683	
LIADH ITIES AND STOCKHOLDEDS, EQUITY					
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:					
	\$	163,886	\$	142 122	
Accounts payable Accrued liabilities	Ф	607,315	Ф	142,132 405,582	
Deferred revenues		1,152,870		777,887	
Total current liabilities					
		1,924,071	-	1,325,601	
Income tax payable		118,072		105,748	
Operating lease liabilities		102,656		64,445	
Other long-term liabilities Total liabilities		174,597		100,024	
		2,319,396		1,595,818	
Commitments and contingencies (Notes 10 and 11)					
Stockholders' equity:					
Preferred stock, \$0.0001 par value (5,000 shares authorized; none issued)		_		_	
Common stock, \$0.0001 par value (200,000 shares authorized; 78,710 and 78,860 issued and outstanding, respectively)		8		8	
Additional paid-in capital		999,006		974,556	
Accumulated other comprehensive income (loss), net		4,326		43,501	
Retained earnings		2,619,374		2,215,800	
Total stockholders' equity		3,622,714		3,233,865	
Total liabilities and stockholders' equity	\$	5,942,110	\$	4,829,683	

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

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

	Commo	n St	ock	Additional	Accumulated Other		
	Shares	A	Amount	Paid-In Capital	Comprehensive Income (Loss), Net	Retained Earnings	Total
Balance as of December 31, 2018	79,778	\$	8	\$ 877,514	\$ (2,774)	\$ 378,143	\$ 1,252,891
Net income	_		_	_	_	442,776	442,776
Net change in unrealized gains (losses) from investments	_		_	_	299	_	299
Net change in foreign currency translation adjustment	_		_	_	1,787	_	1,787
Issuance of common stock relating to employee equity compensation plans	542		_	17,907	_	_	17,907
Tax withholdings related to net share settlements of equity awards	_		_	(57,676)	_	_	(57,676)
Common stock repurchased and retired	(1,887)		_	(18,992)	_	(381,007)	(399,999)
Stock-based compensation				88,184			88,184
Balance as of December 31, 2019	78,433		8	906,937	(688)	439,912	1,346,169
Net income	_		_	_	_	1,775,888	1,775,888
Net change in unrealized gains (losses) from investments	_		_	_	(194)	_	(194)
Net change in foreign currency translation adjustment	_		_	_	44,383	_	44,383
Issuance of common stock relating to employee equity compensation plans	427		_	20,314	_	_	20,314
Tax withholdings related to net share settlements of equity awards	_		_	(51,122)	_	_	(51,122)
Stock-based compensation				 98,427		 	98,427
Balance as of December 31, 2020	78,860		8	974,556	43,501	2,215,800	3,233,865
Net income	_		_	_	_	772,020	772,020
Net change in unrealized gains (losses) from investments	_		_	_	(495)	_	(495)
Net change in foreign currency translation adjustment	_		_	_	(38,680)	_	(38,680)
Issuance of common stock relating to employee equity compensation plans	442		_	25,623	_	_	25,623
Tax withholdings related to net share settlements of equity awards	_		_	(108,917)	_	_	(108,917)
Common stock repurchased and retired	(592)		_	(6,592)	_	(368,446)	(375,038)
Stock-based compensation				114,336			 114,336
Balance as of December 31, 2021	78,710	\$	8	\$ 999,006	\$ 4,326	\$ 2,619,374	\$ 3,622,714

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,						
		2021	2020		2019		
CASH FLOWS FROM OPERATING ACTIVITIES:							
Net income	\$	772,020	\$ 1,775,888	\$	442,776		
Adjustments to reconcile net income to net cash provided by operating activities:							
Deferred taxes		15,455	(1,491,577)	307		
Depreciation and amortization		108,729	93,538		78,990		
Stock-based compensation		114,336	98,427		88,184		
Non-cash operating lease cost		26,807	22,467		18,475		
Allowance for doubtful accounts provisions		2,814	12,073		5,853		
Arbitration award gain		(43,403)	_		_		
Impairments on long-lived assets		_	_		28,498		
Equity in losses of investee		_	_		7,528		
Gain on lease terminations		_	_		(6,792)		
Gain from sale of equity method investment		_	_		(15,769)		
Other non-cash operating activities		21,549	21,670	ı	24,007		
Changes in assets and liabilities, net of effects of acquisition:							
Accounts receivable		(262,066)	(139,777)	(121,014)		
Inventories		(112,450)	(29,110)	(58,269)		
Prepaid expenses and other assets		(124,626)	(21,130)	(31,529)		
Accounts payable		19,747	52,206		22,099		
Accrued and other long-term liabilities		158,543	42,168	1	60,240		
Long-term income tax payable		12,449	(2,802)	14,611		
Deferred revenues		462,640	228,133		189,075		
Net cash provided by operating activities		1,172,544	662,174	. –	747,270		
CASH FLOWS FROM INVESTING ACTIVITIES:			. <u> </u>				
Acquisition, net of cash acquired		(8,002)	(420,788)	_		
Purchase of property, plant and equipment		(401,098)	(154,916		(149,707)		
Purchase of marketable securities		(200,928)	(5,341	,	(693,284)		
Proceeds from maturities of marketable securities		498	42,641		290,754		
Proceeds from sales of marketable securities		3,114	278,817		194,677		
Repayment on unsecured promissory note		4,594	26,925		21,820		
Proceeds from arbitration award		43,403					
Other investing activities		(5,011)	1,156		(14,704)		
Net cash used in investing activities		(563,430)	(231,506		(350,444)		
CASH FLOWS FROM FINANCING ACTIVITIES:		(303,430)	(251,500	<u>,</u> _	(550,444)		
Proceeds from issuance of common stock		25,623	20,314		17,907		
Common stock repurchases		(375,038)	20,31		(399,999)		
Payroll taxes paid upon the vesting of equity awards		(108,917)	(51,122		(57,675)		
Purchase of finance lease		(100,31/)	(31,122		(45,773)		
Net cash used in financing activities	<u></u>	(458,332)	(30,808)		(485,540)		
Effect of foreign exchange rate changes on cash, cash equivalents, and restricted cash		(12,117)	10,480		2,282		
Net increase (decrease) in cash, cash equivalents, and restricted cash		138,665	410,340		(86,432)		
Cash, cash equivalents, and restricted cash at beginning of year		961,474	551,134		637,566		
Cash, cash equivalents, and restricted cash at end of year	\$	1,100,139	\$ 961,474	. \$	551,134		

 $\label{thm:companying} \textit{ notes are an integral part of these consolidated financial statements.}$

ALIGN TECHNOLOGY, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Business Description

Align Technology, Inc. ("We", "Our", or "Align") was incorporated in April 1997 in Delaware. Align is a global medical device company primarily engaged in the design, manufacture and marketing of Invisalign® clear aligners, iTero® intraoral scanners, services for orthodontics, restorative and aesthetic dentistry and exocad® computer-aided design and computer-aided manufacturing ("CAD/CAM") software for dental laboratories and dental practitioners. We also market and sell consumer products that are complementary to our doctor-prescribed principal products under the Invisalign brand, including retainers, aligner cases (clamshells), teeth whitening products and cleaning solutions (crystals, foam and other material) (collectively "Consumer Products"). Our primary goal is to establish clear aligners as the principal solution for the treatment of malocclusions and our Invisalign system as the treatment solution of choice by orthodontists, general dental practitioners and patients globally, our intraoral scanning platform as the preferred scanning protocol for digital dental scans, and our exocad CAD/CAM software as the solution of choice for dental labs. Our corporate headquarters is located in Tempe, Arizona, which moved from San Jose, California effective January 1, 2021, and we have offices worldwide. Our Americas regional headquarters is located in Raleigh, North Carolina; our European, Middle East and Africa ("EMEA") regional headquarters is located in Rotkreuz, Switzerland; and our Asia Pacific ("APAC") regional headquarters is located in Singapore. We have two operating segments: (1) Clear Aligner, known as the Invisalign system, and (2) Imaging Systems and CAD/CAM services ("Systems and Services"), known as the iTero intraoral scanner and CAD/CAM services.

Basis of Presentation and Preparation

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

Out-of-Period Adjustments

For the year ended December 31, 2021 and 2020, we recorded out-of-period corrections that resulted in tax benefits of \$16.0 million and \$12.7 million, respectively, in our Consolidated Statement of Operations. We do not believe these out-of-period adjustments are material to the interim or annual consolidated financial statements for the respective reporting period or to any of the related prior periods.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles ("GAAP") in the United States of America ("U.S.") requires our management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, useful lives of intangible assets and property and equipment, long-lived assets and goodwill, income taxes and contingent liabilities, the fair values of financial instruments, stock-based compensation and 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:

 $\mathit{Level}\ 1$ - Quoted (unadjusted) prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. We obtain fair values for our Level 2 investments. Our custody bank and asset managers independently use

professional pricing services to gather pricing data which may include quoted market prices for identical or comparable financial instruments, or inputs other than quoted prices that are observable either directly or indirectly, and we are ultimately responsible for these underlying estimates.

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

Cash and Cash Equivalents

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

Restricted Cash

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

Marketable Securities

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

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

Variable Interest Entities

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

Investments in Privately Held Companies

Investments in privately held companies in which we can exercise significant influence but do not own a majority equity interest or otherwise control are accounted for under the equity method. We record our share of their operating results within equity in losses of investee, net of tax, in our Consolidated Statement of Operations.

Investments in privately held companies in which we cannot exercise significant influence and do not own a majority equity interest or otherwise control are accounted for under the measurement alternative. Under the measurement alternative, the carrying value of our equity investment is adjusted to fair value for observable transactions for identical or similar investments of the same issuer. Investments in equity securities are reported on our Consolidated Balance Sheet as other assets,

and we periodically evaluate them for impairment. We record any change in carrying value of our equity securities, in other income (expense), net in our Consolidated Statement of Operations.

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 and do not subject us to material balance sheet risk due to fluctuations in foreign currency exchange rates. The gains and losses on these forward contracts are intended to offset the gains and losses in the underlying foreign currency denominated monetary assets and liabilities being economically hedged. We do not enter into foreign currency forward contracts for trading or speculative purposes. The net gain or loss from the settlement of these foreign currency forward contracts is recorded in other income (expense), net in the Consolidated Statement of Operations.

Foreign Currency

For our international subsidiaries, we analyze on an annual basis or more often if necessary, if a significant change in facts and circumstances indicate that the functional currency has changed. For international subsidiaries where the local currency is the functional currency, adjustments from translating financial statements from the local currency to the U.S. dollar reporting currency are recorded as a separate component of accumulated other comprehensive income (loss), net in the stockholders' equity section of the Consolidated Balance Sheet. This foreign currency translation adjustment reflects the translation of the balance sheet at period end exchange rates, and the income statement at the transaction date or average exchange rate in effect during the period. The foreign currency revaluation that are derived from monetary assets and liabilities stated in a currency other than functional currency are included in other income (expense), net. For the year ended December 31, 2021, 2020 and 2019, we had foreign currency net gains (losses) of \$(13.3) million, \$6.8 million and \$(2.0) million, respectively.

Certain Risks and Uncertainties

Our operating results depend to a significant extent on our ability to market and develop our products. The life cycles of our products are difficult to estimate due, in part, to the effect of future product enhancements and competition. Our inability to successfully develop and market our products as a result of competition or other factors would have a material adverse effect on our business, financial condition and results of operations.

The U.S. Food and Drug Administration ("FDA") and similar international agencies regulate the design, manufacture, distribution, pre-clinical and clinical study, clearance and approval of medical devices. Products developed by us may require approvals or clearances from the FDA or other international regulatory agencies prior to commercialized sales. There can be no assurance that our products will receive any of the required approvals or clearances. If we were denied approval or clearance or such approval was delayed, it may have a material adverse impact on us.

Our cash and investments are held primarily by four 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, commercial paper, certificates of deposits, corporate bonds, asset-backed securities, municipal bonds and U.S. government agency bonds and treasury bonds and periodically evaluate them for credit losses. Such credit losses have not been material to our financial statements.

We provide credit to customers in the normal course of business. Collateral is not required for accounts receivable but ongoing evaluations of customers' credit worthiness are performed. We maintain an allowance for potential credit losses for uncollectible accounts and such losses have been within management's expectations. No individual customer accounted for 10% or more of our accounts receivable at December 31, 2021 or 2020 or net revenues for the year ended December 31, 2021, 2020 or 2019.

We have manufacturing facilities located in Juarez, Mexico where we conduct our aligner fabrication, distribution and perform certain services and in Ziyang, China where we fabricate aligners primarily for China and other APAC markets. In addition, we produce our handheld intraoral scanner wand, perform final scanner assembly and repair our scanners at our facilities in Ziyang, China and Or Yehuda, Israel and service and repair certain scanners in Juarez, Mexico. In the second quarter of 2021, we announced the start of a multi-million dollar project to bring operational facilities closer to our customers through the expansion of our manufacturing operations in Wroclaw, Poland. Expected to begin serving doctors during the first half of 2022, the new aligner fabrication facility will be our third and allow us to more quickly and effectively serve tens of thousands of customers throughout EMEA. Additionally, in the third quarter of 2021, we opened our multi-story iTero scanner and services facilities in Petach Tikva, Israel to further the design and development of our portfolio of iTero intraoral scanners, imaging systems and services. Our digital treatment plans using a sophisticated, internally developed computer-modeling

program are located in multiple international locations to support our customers within the regions. Our reliance on international operations exposes us to related risks and uncertainties, including difficulties in staffing and managing international operations such as hiring and retaining qualified personnel; controlling production volume and quality of manufacture; political, social and economic instability; interruptions and limitations in telecommunication services; product and material transportation delays or disruption; trade restrictions and changes in tariffs; import and export license requirements and restrictions; fluctuations in foreign currency exchange rates; and potential adverse tax consequences. If any of these risks materialize, our international manufacturing operations, as well as our operating results, may be harmed.

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.

Due to the COVID-19 pandemic, we are subject to a greater degree of uncertainty than normal in making the judgments and estimates needed to apply our significant accounting policies. The full extent to which the pandemic, including as a result of any new variants, business restrictions or lockdowns, and the impact of vaccinations, will directly or indirectly impact our business, results of operations, cash flows, and financial condition will depend on future developments that are highly uncertain and cannot be accurately determined. Further, we could also be materially adversely affected by supply chain disruptions, including shortages and inflationary pressures, uncertain or reduced demand, labor shortages, delays in collection of outstanding receivables and the impact of any initiatives or programs that we may undertake to address financial and operational challenges faced by our customers.

Accounts Receivable, net

Trade accounts receivable are recorded at the invoiced amount. Accounts receivable, net includes allowances for doubtful accounts for any potentially uncollectible amounts. We periodically assess the adequacy of the allowance for doubtful accounts by reviewing the accounts receivable on a collective basis by considering factors such as aging of the receivables and customers' expected ability to pay, and on an individual basis for specific customers with known disputes or collectability issues. In determining the amount of the allowance for doubtful accounts, we also evaluate the creditworthiness of customers, current market conditions and forecasts of future economic conditions to make any adjustments. Actual write-offs have not materially differed from the estimated allowances.

Inventories

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

Property, Plant and Equipment, net

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

Leases

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

Business Combinations

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

Goodwill and Finite-Lived Acquired Intangible Assets

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

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

Impairment of Goodwill and Long-Lived Assets

Goodwill

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

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

Long-Lived Assets

We evaluate long-lived assets (including finite-lived intangible assets) for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. An asset or asset group is considered impaired if its carrying amount exceeds the future undiscounted net cash flows that the asset or asset group is expected to generate. Factors we consider important which could trigger an impairment review include significant negative industry or economic trends, significant loss of customers and changes in the competitive environment. If an asset or asset group is considered to be impaired, the impairment to be recognized is calculated as the amount by which the carrying amount of the asset or asset group exceeds its fair market value. Our estimates of future cash flows attributable to our long-lived assets require significant judgment based on our historical and anticipated results and are subject to many assumptions. The estimation of fair value utilizing a discounted cash flow approach includes numerous uncertainties which require our significant judgment when making assumptions of expected growth rates and the selection of discount rates, as well as assumptions regarding general economic and business conditions, and the structure that would yield the highest economic value, among other factors. Refer to *Note 6 "Goodwill and Intangible Assets" of Notes to Consolidated Financial Statements* for details on intangible long-lived assets.

Development Costs for Internal Use Software

Internally developed software includes enterprise-level business software that we customize to meet our specific operational needs. Such capitalized costs include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related costs for employees, who are directly associated with the development of the applications. There were no significant internally developed software costs capitalized in 2021 or 2020.

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

Product Warranty

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

Clear Aligner

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

Systems and Services

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

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

Revenue Recognition

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

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

Clear Aligner

We enter into contracts ("treatment plan(s)") that involve multiple future performance obligations. Invisalign Comprehensive, Invisalign First, Invisalign Moderate, 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, and Invisalign Go and Invisalign Go Plus includes optional additional aligners at no charge for a period of up to two years after initial shipment.

Our treatment plans comprise the following performance obligations that also represent distinct deliverables: initial aligners, the option of additional aligners, case refinement, and replacement aligners. We take the practical expedient to consider shipping and handling costs as activities to fulfill the performance obligation. We allocate revenues for each 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. We also consider usage rates, which is the number of times a customer is expected to order additional aligners. Our process for estimating usage rates requires significant judgment and evaluation of inputs, including historical usage data by region, country and channel. We recognize the revenues upon shipment, as the customers obtain physical possession and we have enforceable rights to payment. As we collect most consideration upfront, we consider whether a significant financing component exists; however, as the delivery of the performance obligations are at the customer's discretion, we conclude that no significant financing component exists.

Systems and Services

We sell intraoral scanners and CAD/CAM services through both our direct sales force and distribution partners. The intraoral scanner sales price includes one year of warranty and unlimited scanning services. The customer may also select, for additional fees, extended warranty and unlimited scanning services for periods beyond the initial year. When intraoral scanners are sold with an unlimited scanning service agreement and/or extended warranty, we allocate revenues based on the respective SSP of the scanner and the subscription service. We estimate the SSP of each element, taking into consideration same or similar historical prices as well as our 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. 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 historical prices. Revenues related to the software license are recognized upfront and revenues related to the maintenance and support are recognized over time. For both scanner and service sales, most consideration is collected upfront and in cases where there are payment plans, consideration is collected within one year and, therefore, there are no significant financing components.

Volume Discounts

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

Accrued Sales Return Reserve

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

Costs to Obtain a Contract

We offer a variety of commission plans to our salesforce; each plan has multiple components. To match the costs to obtain a contract to the associated revenues, we evaluate the individual components and capitalize the eligible components, recognizing the costs over the treatment period. The costs to obtain contracts were \$31.1 million and \$22.8 million as of December 31, 2021 and 2020, respectively, and are included in other assets in our Consolidated Balance Sheets. We recognized amortization on our costs to obtain a contract of \$17.0 million, \$10.1 million, and \$7.2 million during the year ended December 31, 2021, 2020, and 2019, respectively, which is included in selling, general and administrative expenses in our Consolidated Statements of Operations.

Unfulfilled Performance Obligations for Clear Aligners and Scanners

Our unfulfilled performance obligations, including deferred revenues and backlog, as of December 31, 2021 and the estimated revenues expected to be recognized in the future related to these performance obligations are \$1,307.3 million. This includes performance obligations from the Clear Aligner segment, primarily the shipment of additional aligners, which are fulfilled over six months to five years. This also includes the performance obligations from the Systems and Services segment, primarily services and support, which are fulfilled over one to five years, and contracted deliveries of additional scanners. The estimate includes both product and service unfulfilled performance obligations and the time range reflects our best estimate of

when we will transfer control to the customer and may change based on customer usage patterns, timing of shipments, readiness of customers' facilities for installation, and manufacturing availability.

Contract Balances

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

Shipping and Handling Costs

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

Legal Proceedings and Litigations

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

Research and Development

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

Advertising Costs

The cost of advertising and media is expensed as incurred. For the year ended December 31, 2021, 2020 and 2019, we incurred advertising costs of \$325.6 million, \$161.0 million and \$119.1 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 stock awards and employee stock purchase plan shares. We use a Monte Carlo simulation model to estimate the fair value of market-performance based restricted stock units ("MSUs") which requires the input of assumptions, including expected term, stock price volatility and the risk-free rate of return. In addition, judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. 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. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

Income Taxes

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

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the applicable

tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities which are included in our Consolidated Balance Sheets.

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

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

During fiscal 2020, we completed an intra-entity transfer of certain intellectual property rights and fixed assets to our Swiss subsidiary, which resulted in the recognition of deferred tax assets and related tax benefits. Refer to *Note 15 "Income Taxes" of Notes to Consolidated Financial Statements* for more information. The establishment of deferred tax assets from the intra-entity transfer of intangible assets required us to make significant estimates and assumptions to determine the fair value of intellectual property rights transferred which include, but are not limited to, our expectations of growth rates in revenue, margins, future cash flows, and discount rates. The accuracy of these estimates could be affected by unforeseen events or actual results, and the sustainability of our future tax benefits is dependent upon the acceptance of these valuation estimates and assumptions by the taxing authorities.

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

Common Stock Repurchase

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

Recent Accounting Pronouncements

(i) New Accounting Updates Recently Adopted

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2019-12, "*Income Taxes* (*Topic 740*) *Simplifying the Accounting for Income Taxes*," to enhance and simplify various aspects of the income tax accounting guidance. The amendment removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The amendments are effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2020. Adoption of this standard in the first quarter of fiscal year 2021 did not have a material impact on our consolidated financial statements or related disclosures.

(ii) Recent Accounting Updates Not Yet Effective

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

Note 2. Financial Instruments

Cash, Cash Equivalents and Marketable Securities

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

									Rej	ported as:						
Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Fair Value	Cash and Cash Equivalents		Marketable securities, short- term		securities, short		sh and Cash securities, s			arketable rities, long- term
\$ 754,802	\$		\$		\$	754,802	\$	754,802	\$		\$	_				
343,012		_		(2)		343,010		343,010		_		_				
115,507		9		(398)		115,118		1,042		35,065		79,011				
42,976		_		(48)		42,928		_		22,251		20,677				
32,031		_		(40)		31,991		_		10,999		20,992				
7,628				(15)		7,613		516		3,657		3,440				
 1,201				(1)		1,200						1,200				
\$ 1,297,157	\$	9	\$	(504)	\$	1,296,662	\$	1,099,370	\$	71,972	\$	125,320				
¢	\$ 754,802 343,012 115,507 42,976 32,031 7,628 1,201	Cost \$ 754,802 \$ 343,012 115,507 42,976 32,031 7,628 1,201	Amortized Cost Unrealized Gains \$ 754,802 \$ — 343,012 — 115,507 9 42,976 — 32,031 — 7,628 — 1,201 —	Amortized Cost Unrealized Gains \$ 754,802 \$ — 343,012 — 115,507 9 42,976 — 32,031 — 7,628 — 1,201 —	Amortized Cost Unrealized Gains Unrealized Losses \$ 754,802 \$ — \$ — 343,012 — (2) 115,507 9 (398) 42,976 — (48) 32,031 — (40) 7,628 — (15) 1,201 — (1)	Amortized Cost Unrealized Gains Unrealized Losses \$ 754,802 \$ — \$ 343,012 — (2) 115,507 9 (398) 42,976 — (48) 32,031 — (40) 7,628 — (15) 1,201 — (1)	Amortized Cost Unrealized Gains Unrealized Losses Fair Value \$ 754,802 \$ — \$ 754,802 343,012 — (2) 343,010 115,507 9 (398) 115,118 42,976 — (48) 42,928 32,031 — (40) 31,991 7,628 — (15) 7,613 1,201 — (1) 1,200	Amortized Cost Unrealized Gains Unrealized Losses Fair Value Control Contro	Amortized Cost Unrealized Gains Unrealized Losses Fair Value Cash and Cash Equivalents \$ 754,802 \$ — \$ — \$ 754,802 \$ 754,802 343,012 — (2) 343,010 343,010 115,507 9 (398) 115,118 1,042 42,976 — (48) 42,928 — 32,031 — (40) 31,991 — 7,628 — (15) 7,613 516 1,201 — (1) 1,200 —	Amortized Cost Unrealized Gains Gross Unrealized Losses Fair Value Cash and Cash Equivalents Security Security \$ 754,802 \$ — \$ — \$ 754,802 \$ 754,802 \$ 754,802 \$ \$ 754,802 \$ \$ 754,802 \$ \$ 754,802 \$ 754,802	Amortized Cost Unrealized Gains Unrealized Losses Fair Value Cash and Cash Equivalents securities, short-term \$ 754,802 \$ — \$ 754,802 \$ 754,802 \$ — 343,012 — (2) 343,010 343,010 — 115,507 9 (398) 115,118 1,042 35,065 42,976 — (48) 42,928 — 22,251 32,031 — (40) 31,991 — 10,999 7,628 — (15) 7,613 516 3,657 1,201 — (1) 1,200 — —	Amortized Cost Unrealized Gains Unrealized Losses Fair Value Cash and Cash Equivalents Marketable securities, short-term Marketable securities, short-term \$ 754,802 \$ — \$ — \$ 754,802 \$ 754,802 \$ — \$ 343,012 — (2) 343,010 343,010 — — 115,507 9 (398) 115,118 1,042 35,065 — 42,976 — (48) 42,928 — 22,251 — 32,031 — (40) 31,991 — 10,999 — 7,628 — (15) 7,613 516 3,657 — 1,201 — (1) 1,200 — — — —				

As of December 31, 2020, we held \$441.6 million of cash and \$519.2 million of money market funds which were reported as cash and cash equivalents on our Consolidated Balance Sheet. We had no short-term or long-term marketable securities as of December 31, 2020. Net realized and unrealized gains and losses were not material for the year ended December 31, 2021, 2020 and 2019.

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

	December 31, 2021
Due in 1 year or less	\$ 59,737
Due in 1 year through 5 years	139,113
Total	\$ 198,850

The securities that we invest in are generally deemed to be low risk based on their credit ratings from the major rating agencies. The longer the duration of these securities, the more susceptible they are to changes in market interest rates and bond yields. As interest rates increase, those securities purchased at a lower yield show a mark-to-market unrealized loss. Our unrealized losses as of December 31, 2021 are primarily due to changes in interest rates and credit spreads. We had no marketable securities that have been in a continuous material unrealized loss position for greater than twelve months as of December 31, 2021.

Fair Value Measurements

The following tables summarize our financial assets measured at fair value as of December 31, 2021 and 2020 (in thousands):

Description	Balanc	e as of December 31, 2021	Level 1	Level 2	Level 3
Cash equivalents:					
Money market funds	\$	343,010	\$ 343,010	\$ _	\$ _
Corporate bonds		1,042	_	1,042	_
Municipal bonds		516	_	516	_
Short-term investments:					
U.S. government treasury bonds		22,251	22,251	_	_
Corporate bonds		35,065	_	35,065	_
Municipal bonds		3,657	_	3,657	_
Asset-backed securities		10,999	_	10,999	_
Long-term investments:					
U.S. government treasury bonds		20,677	20,677	_	_
Corporate bonds		79,011	_	79,011	_
Municipal bonds		3,440	_	3,440	_
U.S. government agency bonds		1,200	_	1,200	_
Asset-backed securities		20,992	_	20,992	_
Prepaid expenses and other current assets:					
Israeli funds		3,841	_	3,841	_
Other assets:					
Investments in privately held companies ¹		8,621		_	8,621
	\$	554,322	\$ 385,938	\$ 159,763	\$ 8,621

The adjustment to the carrying value of our equity investments in privately held companies without readily determinable fair value are not material during the year ended December 31, 2021, 2020 and 2019.

Description	Balanc	te as of December 31, 2020	Level 1	Level 2	Level 3
Cash equivalents:					
Money market funds	\$	519,228	\$ 519,228	\$ _	_
Prepaid expenses and other current assets:					
Israeli funds		3,500	_	3,500	_
Current unsecured promissory note		5,408	_	_	5,408
	\$	528,136	\$ 519,228	\$ 3,500	\$ 5,408

Derivatives Not Designated as Hedging Instruments

Recurring foreign currency forward contracts

We enter into foreign currency forward contracts to minimize the short-term impact of foreign currency exchange rate fluctuations on certain trade and intercompany receivables and payables. These forward contracts are classified within Level 2 of the fair value hierarchy. As a result of the settlement of foreign currency forward contracts, during the year ended December 31, 2021, 2020 and 2019, we recognized a net gain of \$18.8 million, a net loss of \$22.1 million and a net gain of \$3.2 million, respectively. As of December 31, 2021 and 2020, the fair value of foreign exchange forward contracts outstanding were not material.

The following table presents the gross notional value of all our foreign exchange forward contracts outstanding as of December 31, 2021 and 2020 (in thousands):

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

	December 31, 2020		
	Local Currency Amount		al Contract unt (USD)
Euro	€126,300	\$	155,125
Chinese Yuan	¥936,000		143,393
Canadian Dollar	C\$65,000		50,791
British Pound	£32,300		43,879
Japanese Yen	¥4,249,000		41,222
Brazilian Real	R\$142,000		27,264
Israeli Shekel	ILS74,000		23,094
Mexican Peso	M\$140,000		7,002
Australian Dollar	A\$5,800		4,447
Swiss Franc	CHF3,700		4,191
		\$	500,408

Other foreign currency forward contract

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

Note 3. Balance Sheet Components

Inventories consist of the following (in thousands):

	December 31,				
	2021	2020			
Raw materials	\$ 123,234	\$	76,404		
Work in progress	51,706		31,393		
Finished goods	55,290		31,440		
Total inventories	\$ 230,230	\$	139,237		

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

	December 31,				
	2021		2020		
Prepaid expenses	\$ 70,218	\$	30,069		
Other current assets	125,087		61,685		
Total prepaid expenses and other current assets	\$ 195,305	\$	91,754		

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

		Decem	iber 31,	
	Generally Used Estimated Useful Life	2021		2020
Clinical and manufacturing equipment	Up to 10 years	\$ 452,876	\$	372,077
Building	20 years	310,344		244,166
Leasehold improvements	Lease term ¹	61,289		63,541
Computer software and hardware	3 years	117,986		108,068
Land	_	58,869		34,598
Furniture, fixtures and other	2-5 years	71,977		50,031
Construction in progress	_	367,686		163,492
Total		1,441,027		1,035,973
Less: Accumulated depreciation and impairment charges		(359,101)		(301,252)
Total property, plant and equipment, net		\$ 1,081,926	\$	734,721

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

Depreciation was \$92.1 million, \$80.1 million and \$73.1 million for the year ended December 31, 2021, 2020 and 2019, respectively.

Accrued liabilities consist of the following (in thousands):

	December 31,			
		2021		2020
Accrued payroll and benefits	\$	288,355	\$	170,106
Accrued expenses		67,169		42,536
Accrued property, plant and equipment		46,561		27,692
Accrued sales and marketing expenses		41,387		34,488
Accrued professional fees		31,457		20,617
Accrued income taxes		33,838		30,130
Current operating lease liabilities		22,719		21,735
Other accrued liabilities		75,829		58,278
Total accrued liabilities	\$	607,315	\$	405,582

Accrued warranty as of December 31, 2021 and 2020, which is included in the "Other accrued liabilities" category of the accrued liabilities table above, consists of the following activity (in thousands):

Accrued warranty as of December 31, 2019	\$ 11,205
Charged to cost of net revenues	12,581
Actual warranty expenditures	(11,171)
Accrued warranty as of December 31, 2020	 12,615
Charged to cost of net revenues	18,213
Actual warranty expenditures	 (14,659)
Accrued warranty as of December 31, 2021	\$ 16,169

Deferred revenues consist of the following (in thousands):

		December 31,			
	2021		2020		
Deferred revenues - current	\$ 1,152	870 \$	777,887		
Deferred revenues - long-term ¹	136	684	62,551		

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

During the year ended December 31, 2021 and 2020, we recognized \$3,952.6 million and \$2,471.9 million of net revenues, respectively, of which \$481.1 million and \$341.9 million was included in the deferred revenues balance at December 31, 2020 and December 31, 2019, respectively.

Note 4. Leases

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

	Year Ended December 31,						
Lease Cost	2021 2020				2019		
Operating lease cost ¹	\$	33,241	\$	27,825	\$	22,778	
Variable lease cost ²		11,134		1,429		1,899	
Total lease cost	\$	44,375	\$	29,254	\$	24,677	

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

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

	December 31,			
Remaining Lease Term and Discount Rate	2021	2020		
Weighted average remaining lease term (in years)	7.8	7.4		
Weighted average discount rate	3.2 %	4.2 %		

As of December 31, 2021, the future payments related to our operating lease liabilities are as follows (in thousands):

Fiscal Year Ending December 31,	Operating Leases
2022	\$ 26,035
2023	24,620
2024	18,284
2025	15,517
2026	13,113
Thereafter	45,461
Total lease payments	143,030
Less: Imputed interest	(17,655)
Total lease liabilities	\$ 125,375

As of December 31, 2021, we had additional leases that have not yet commenced with future lease payments of \$17.8 million. These leases will commence during 2022 with non-cancelable lease terms of two to seven years.

Note 5. Business Combination

On April 1, 2020, we completed the acquisition of privately-held exocad for a total purchase consideration of \$430.0 million and exocad became a wholly-owned subsidiary. exocad is a German dental CAD/CAM software company that offers fully integrated workflows to dental labs and dental practices.

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

The allocation of purchase price to assets acquired and liabilities assumed based on estimated fair values is as follows (in thousands):

Goodwill ¹	\$ 340,181
Identified intangible assets	118,700
Cash and cash equivalents	9,190
Deferred tax liabilities	(35,419)
Other assets (liabilities), net	 (2,674)
Total	\$ 429,978

¹ None of this goodwill is deductible for tax purposes.

The following table presents details of the identified intangible assets acquired (in thousands, except years):

Amortization Period (in years)		Fair Value
10	\$	87,000
10		21,500
7		9,800
N/A		400
	\$	118,700
	Amortization Period (in years) 10 10 7	Amortization Period (in years) 10 \$ 10 7

We believe the amount of purchased intangible assets recorded above represent the fair values and approximate the amount a market participant would pay for these intangible assets as of the acquisition date.

Existing technology represents the estimated fair value of exocad's core technology that has reached technological feasibility. We valued the existing technology using the multi-period excess earnings method under the income approach. The economic useful life of existing technology was determined by considering the life cycle of the technology and related cash flows.

Customer relationships represent the fair value of future projected revenue that will be derived from sales of products to existing customers. Customer relationships were valued using the with-and-without method under the income approach. The economic useful life for customer relationships was based on historical customer attrition rates.

Tradenames relates to the exocad tradenames that are recognized within the industry. The fair value was determined using the relief-from-royalty method under the income approach. The economic useful life of tradenames was determined by benchmarking against similar transactions entered into by peer companies.

IPR&D refers to the fair value of projects that are not yet completed but have potential value to the company.

Note 6. Goodwill and Intangible Assets

During the year ended December 31, 2021, we completed an immaterial business combination which increased goodwill and existing technology intangible assets.

Goodwill

The change in the carrying value of goodwill for the year ended December 31, 2021 and 2020, categorized by reportable segments, is as follows (in thousands):

	Clear Aligner	Systems and Services	Total
Balance as of December 31, 2019	\$ 63,924	\$	\$ 63,924
Additions from acquisition	43,500	296,681	340,181
Foreign currency translation adjustments	5,267	35,445	40,712
Balance as of December 31, 2020	 112,691	332,126	444,817
Additions from acquisition	3,646	_	3,646
Foreign currency translation adjustments	(4,129)	(25,787)	(29,916)
Balance as of December 31, 2021	\$ 112,208	\$ 306,339	\$ 418,547

We completed our annual goodwill impairment assessments in 2021 and 2020 and determined there were no impairments.

Intangible Long-Lived Assets

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

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

	Weighted Average Amortization Period (in years)	Gross Carrying Amount as of ecember 31, 2020	Accumulated Amortization	Accumulated pairment Loss	D	Net Carrying Value as of ecember 31, 2020
Existing technology	10	\$ 99,400	\$ (12,719)	\$ (4,328)	\$	82,353
Customer relationships	11	55,000	(21,879)	(10,751)		22,370
Trademarks and tradenames	10	16,600	(2,934)	(4,179)		9,487
Patents and other	8	6,610	(3,785)	_		2,825
		\$ 177,610	\$ (41,317)	\$ (19,258)		117,035
Foreign currency translation						13,037
Total intangible assets					\$	130,072

There were no triggering events in 2021 or 2020 that would cause impairments of our intangible long-lived assets.

The total estimated annual future amortization expense for these acquired intangible assets as of December 31, 2021 is as follows (in thousands):

Fiscal Year	Amortization
2022	\$ 15,692
2023	14,997
2024	13,831
2025	13,455
2026	12,849
Thereafter	 35,732
Total	\$ 106,556

Amortization expense was \$16.6 million, \$13.4 million and \$5.9 million for the year ended December 31, 2021, 2020 and 2019, respectively.

Note 7. Equity Method Investments

On July 25, 2016, we acquired a 17% equity interest, on a fully diluted basis, in SmileDirectClub, LLC ("SDC") for \$46.7 million. Concurrently with the investment, we also entered into a supply agreement to manufacture clear aligners for SDC, which expired on December 31, 2019. The sale of aligners to SDC and the income from the supply agreement were reported in our Clear Aligner business segment. On July 24, 2017, we purchased an additional 2% equity interest in SDC for \$12.8 million. The investment was accounted for as an equity method investment and recorded in our Consolidated Balance Sheet. We recorded our proportional share of SDC's losses within equity in losses of investee, net of tax, in our Consolidated Statement of Operations within our Clear Aligner reportable segment.

As a result of the arbitrator's decision regarding SDC announced on March 5, 2019, we were ordered to tender our SDC equity interest by April 3, 2019 for a purchase price equal to the "capital account" balance as of October 31, 2017 under the terms of the investment. In April 2019, based on the "capital account" value provided by SDC, we entered into an unsecured promissory note with SDC to receive \$54.2 million through February 1, 2021 in exchange for the tender of our membership interests. As a result, we derecognized the equity method investment balance of \$38.4 million in exchange for an unsecured promissory note of \$54.2 million and we recorded the difference of \$15.8 million as a gain in 2019 in other income in our Consolidated Statement of Operations. The unsecured promissory note was paid in full by SDC during the year ended December 31, 2021.

Although we tendered our membership interests pursuant to the arbitrator's decision, the parties did not agree on the amount of the "capital account" balance as of October 31, 2017 or the appropriate repurchase price for the membership units. On July 3, 2019, we filed a demand for arbitration regarding SDC's calculation of the "capital account" balance. On March 12, 2021, the Arbitrator ruled in favor of Align and against SDC and issued an award of \$43.4 million along with interest. The gain of \$43.4 million was recognized as a part of our other income (expense), net in our Consolidated Statement of Operation during the year ended December 31, 2021. Refer to Note 10 "Legal Proceedings" of the Notes to Consolidated Financial Statements included for more information on the arbitration.

Note 8. Credit Facility

On July 21, 2020 we entered into a credit facility for a \$300.0 million unsecured revolving line of credit, with a \$50.0 million letter of credit sublimit, and a maturity date of July 21, 2023 ("2020 Credit Facility"). The 2020 Credit Facility requires us to comply with specific financial conditions and performance requirements. Loans under the 2020 Credit Facility bear interest, at our option, at either a rate based on the reserve adjusted LIBOR for the applicable interest period or a base rate, in each case plus a margin. The base rate is the highest of the credit facility's publicly announced prime rate, the federal funds rate plus 0.50% and one-month LIBOR plus 1.0%. The margin ranges from 1.50% to 2.25% for LIBOR loans and 0.50% to 1.25% for base rate loans. The 2020 Credit Facility allows for an alternative rate to be identified if LIBOR is no longer available. Interest on the loans is payable quarterly in arrears with respect to base rate loans and at the end of an interest period (and at three month intervals if the interest period exceeds three months) in the case of LIBOR loans. The outstanding principal, together with accrued and unpaid interest, is due on the maturity date. As of December 31, 2021, we had no outstanding borrowings under the 2020 Credit Facility and were in compliance with the conditions and performance requirements.

Note 9. Impairments and Other Charges (Gains), net

On March 5, 2019, we announced the outcome of the arbitration regarding SDC (Refer to *Note 10 "Legal Proceedings"* of the *Notes to Consolidated Financial Statements* for SDC legal proceedings discussion) which required Align to close its Invisalign stores and tender Align's equity interest in SDC by April 3, 2019. Accordingly, Align evaluated the ongoing value of the Invisalign stores' operating lease right-of-use assets and related leasehold improvements and other fixed assets and determined that the carrying value of these assets were not recoverable. Align evaluated the fair value of these assets and we considered the market participant's ability to generate economic benefits by using these assets in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use. As a result, in 2019, we recorded impairment losses of \$14.2 million for operating lease right-of-use assets and \$14.3 million of leasehold improvements and other fixed assets. In addition, we also recorded \$1.3 million of employee severance costs and other charges. During 2019, we also negotiated early termination of our Invisalign store leases and recorded lease termination gains of \$6.8 million.

Note 10. Legal Proceedings

2018 Securities Class Action Lawsuit

On November 5, 2018, a class action lawsuit against Align and three of our executive officers was filed in the U.S. District Court for the Northern District of California on behalf of a purported class of purchasers of our common stock. The complaint generally alleged claims under the federal securities laws and sought monetary damages in an unspecified amount and costs and expenses incurred in the litigation. On December 12, 2018, a similar lawsuit was filed in the same court on behalf of a purported class of purchasers of our common stock. On November 29, 2019, the lead plaintiff filed an amended consolidated complaint against Align and two of our executive officers alleging similar claims as the initial complaints on behalf of a purported class of purchasers of our common stock from May 23, 2018 and October 24, 2018. On September 9, 2020, Defendants' motion to dismiss the amended consolidated complaint was granted in part and denied in part. On June 30, 2021, counsel for the parties signed a Stipulation and Agreement of Settlement to resolve all claims for \$16 million. The settlement amount will be funded by insurance proceeds and consequently, we recorded a short term liability and a receivable for this amount in our consolidated financial statements. The Court granted preliminary approval of the settlement on November 2, 2021. A final settlement approval hearing is currently set for April 28, 2022. The settlement is subject to notice to class members and final approval by the Court.

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 behalf of Align, naming as defendants the then current members of our Board of Directors along with certain of our executive officers. The allegations in the complaints are similar to those asserted in the 2018 Securities Class Action Lawsuit, but the complaints assert various state law causes of action, including for breaches of fiduciary duty, insider trading, and unjust enrichment. The complaints seek unspecified monetary damages on behalf of Align, which is named solely as a nominal defendant against whom no recovery is sought, as well as disgorgement and the costs and expenses associated with the litigation, including attorneys' fees. The consolidated action has been stayed pending final disposition of the 2018 Securities Class Action Lawsuit.

On April 12, 2019, a derivative lawsuit was also filed in California Superior Court for Santa Clara County, purportedly on behalf of Align, naming as defendants the members of our Board of Directors along with certain of our executive officers. The allegations in the complaint are similar to those in the derivative suits described above. The matter has been similarly stayed pending final disposition of the 2018 Securities Class Action Lawsuit.

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

2020 Securities Class Action Lawsuit

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

complaint. On April 23, 2021, the Court dismissed the action with prejudice and judgment was entered. Lead plaintiff filed a notice of appeal on April 28, 2021 and filed its opening appeal brief with the United States Court of Appeals for the Ninth Circuit on September 1, 2021. The defendants-appellees filed their answering brief on November 22, 2021. The lead plaintiff-appellant's reply brief was filed on January 12, 2022, and oral argument is set for March 10, 2022. 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 therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

2020 Shareholder Derivative Lawsuit

On May 4, 2020, a derivative lawsuit was filed in the U.S. District Court for the Northern District of California, purportedly on behalf of Align, naming as defendants the members of our Board of Directors along with certain of our executive officers. The allegations in the complaint are similar to those presented in the 2020 Securities Class Action Lawsuit, but this complaint asserts state law claims for breach of fiduciary duty and insider trading. The complaint seeks unspecified monetary damages on behalf of Align, which is named solely as a nominal defendant against whom no recovery is sought, as well as disgorgement and the costs and expenses associated with the litigation, including attorneys' fees. This action is stayed pending resolution of the appeal in the 2020 Securities Class Action Lawsuit. Align believes these claims are without merit. Align is currently unable to predict the outcome of this lawsuit and therefore cannot determine the likelihood of loss nor estimate a range of possible loss.

3Shape Litigation

On February 7, 2022, Align and 3Shape, a Danish corporation, settled their outstanding patent infringement and antitrust litigation, which began in November 2017. The terms of the settlement are confidential, and the settlement is not expected to have a material effect on Align's ongoing operations and financial results. The parties have filed stipulations to stay all proceedings pending completion of the settlement.

Antitrust Class Actions

On June 5, 2020, a dental practice named Simon and Simon, PC doing business as City Smiles brought an antitrust action in the U.S. District Court for the Northern District of California on behalf of itself and a putative class of similarly situated practices seeking monetary damages and injunctive relief relating to Align's alleged market activities in alleged clear aligner and intraoral scanner markets. Plaintiff filed an amended complaint and added VIP Dental Spas as a plaintiff on August 14, 2020. A jury trial is scheduled to begin in this matter on November 20, 2023. Align believes the plaintiffs' claims are without merit and intends to vigorously defend itself.

On May 3, 2021, an individual named Misty Snow brought an antitrust action in the U.S. District Court for the Northern District of California on behalf of herself and a putative class of similarly situated individuals seeking monetary damages and injunctive relief relating to Align's alleged market activities in alleged clear aligner and intraoral scanner markets. Plaintiff filed an amended complaint on July 30, 2021 adding new plaintiffs and various state law claims. Align moved to dismiss the first amended complaint. On September 30, 2021, the Court dismissed the complaint and granted Plaintiffs leave to amend. Plaintiffs filed a second amended complaint on October 21, 2021. Align filed a motion to dismiss the second amended complaint, which the Court granted in part and denied in part. Align believes the plaintiffs' claims are without merit and intends to vigorously defend itself.

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

SDC Dispute

In April 2018, SDC Financial LLC, SmileDirectClub LLC, and the Members of SDC Financial LLC other than the Company (collectively, the "SDC Entities") initiated confidential arbitration proceedings against Align. In an award dated March 4, 2019, ("Award") an arbitrator found that Align breached a restrictive covenant and that Align misused the SDC Entities' confidential information and violated fiduciary duties to SDC Financial LLC. As part of the Award, Align was enjoined from opening new Invisalign stores or providing certain services in physical retail establishments in connection with the marketing and sale of clear aligners in the U.S., and enjoined from using the SDC Entities' confidential information. The arbitrator extended the expiration date of specified aspects of the restrictive covenant to August 18, 2022. The arbitrator also ordered Align to tender its SDC Financial LLC membership interests to the SDC Entities for a purchase price equal to the "capital account" balance as of October 31, 2017, to be determined in accordance with the applicable provisions of the SDC Operating Agreements. No financial damages were awarded to the SDC Entities. The Circuit Court for Cook County, Illinois confirmed the Award on April 29, 2019.

As required by the Award, Align tendered its membership interests for a purchase price that SDC claimed to be Align's "capital account" balance. Align disputed that the SDC Entities properly determined the value of Align's "capital account" balance as of October 31, 2017. Consequently, on July 3, 2019, Align filed a confidential demand for arbitration challenging the propriety of the SDC Entities' determination. On March 12, 2021 the Arbitrator issued a final award in favor of Align and against SDC finding that the SDC entities owed Align an additional \$43.4 million plus interest. SDC paid the amount due to Align on March 17, 2021.

On August 27, 2020, Align initiated a confidential arbitration proceeding against the SDC entities before the American Arbitration Association in San Jose, California. This arbitration relates to the Strategic Supply Agreement ("Supply Agreement") entered into between the parties in 2016. The complaint alleges that the SDC Entities breached the Supply Agreement's terms, causing damages to Align in an amount to be determined. On January 19, 2021, SDC filed a counterclaim alleging that Align breached the Supply Agreement. Align denies the SDC Entities' allegations in the counterclaim and will vigorously defend itself against them. This arbitration hearing is set for July 18-29, 2022.

Align is currently unable to predict the outcome of these disputes and therefore cannot determine the likelihood of loss or success nor estimate a range of possible loss or success, if any.

In addition to the above, in the ordinary course of Align's operations, Align is 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 Align's view of these matters may change in the future as litigation and events related thereto unfold; Align currently does not believe that these matters, individually or in the aggregate, will materially affect Align's financial position, results of operations or cash flows.

Note 11. Commitments and Contingencies

Unconditional Purchase Obligations

On May 29, 2018, we entered into a purchase agreement, as amended, with an existing single source supplier which requires us to purchase aligner material for a minimum amount of approximately \$425.9 million over five years through 2022. On June 24, 2021, we amended the agreement which requires an additional minimum align material purchase of approximately \$348.0 million from 2023 through 2026. As of December 31, 2021, our remaining commitment under this agreement totaled \$419.6 million.

On October 30, 2020, we entered into a subscription agreement with a software company to renew our license for a total consideration of \$95.2 million. As of December 31, 2021, we had a remaining commitment of \$47.6 million which is expected to be paid through 2024.

On December 6, 2020, we entered into a supply agreement for certain components used for our manufacturing operations. As of December 31, 2021, we had purchase commitments of \$140.5 million which is expected to be paid through 2025.

On December 14, 2021, we entered into a letter of intent to amend a promotional rights agreement with a third-party which includes advertising and media coverage. As of December 31, 2021, we had a remaining commitment of \$79.2 million which is expected to be paid through 2026.

Off-Balance Sheet Arrangements

As of December 31, 2021, we had no material off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources other than certain items disclosed in the Unconditional Purchase Obligations section above.

Indemnification Provisions

In the normal course of business to facilitate transactions in our services and products, we indemnify certain parties: customers, vendors, lessors, and other parties with respect to certain matters, including, but not limited to, services to be provided by us and intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with our directors and our executive officers that will require us, among other things, to indemnify

them against certain liabilities that may arise by reason of their status or service as directors or officers. Several of these agreements limit the time within which an indemnification claim can be made and the amount of the claim.

It is not possible to make a reasonable estimate of the maximum potential amount under these indemnification agreements due to the unique facts and circumstances involved in each particular agreement. Additionally, we have a limited history of prior indemnification claims and the payments we have made under such agreements have not had a material adverse effect on our results of operations, cash flows or financial position. However, to the extent that valid indemnification claims arise in the future, future payments by us could be significant and could have a material adverse effect on our results of operations or cash flows in a particular period. As of December 31, 2021, we did not have any material indemnification claims that were probable or reasonably possible.

Note 12. Stockholders' Equity

Common Stock

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

Stock-Based Compensation Plans

Our 2005 Incentive Plan, as amended, provides for the granting of incentive stock options, non-statutory stock options, restricted stock units ("RSUs"), market-performance based restricted stock units ("MSUs"), 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 unit, market-performance based restricted stock units, performance share or performance unit ("full value awards") are counted against the authorized share reserve as one and nine-tenths (19/10) shares for every one (1) share subject to the award, and any shares canceled that were counted as one and nine-tenths against the plan reserve will be returned at the same ratio.

As of December 31, 2021, the 2005 Incentive Plan, as amended, has a total reserve of 27,783,379 shares for issuance of which 4,244,723 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 stockbased compensation plans.

Summary of Stock-Based Compensation Expense

The stock-based compensation related to our stock-based awards and employee stock purchase plan for the year ended December 31, 2021, 2020 and 2019 is as follows (in thousands):

	Year Ended December 31,						
	2021	2020			2019		
Cost of net revenues	\$ 5,633	\$	4,719	\$	5,154		
Selling, general and administrative	90,659		78,500		69,817		
Research and development	18,044		15,208		13,213		
Total stock-based compensation	\$ 114,336	\$	98,427	\$	88,184		

The income tax benefit related to stock-based compensation was \$13.8 million, \$11.9 million and \$10.3 million for the year ended December 31, 2021, 2020 and 2019, respectively.

Restricted Stock Units

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, 2021 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, 2020	632	\$	243.55	_			
Granted	166		600.10				
Vested and released	(265)		216.73				
Forfeited	(41)		350.75				
Unvested as of December 31, 2021	492	\$	369.17	1.1	\$ 323,239		

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 2021 by the number of unvested RSUs) that would have been received by the unit holders had all RSUs been vested and released as of the last trading day of 2021. This amount will fluctuate based on the fair market value of our stock. During 2021, of the 264,655 shares vested and released, 78,930 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 185,725 shares.

The total fair value of RSUs vested as of their respective vesting dates during 2021, 2020 and 2019 was \$158.8 million, \$89.6 million and \$112.4 million, respectively. The weighted average grant date fair value of RSUs granted during 2021, 2020 and 2019 was \$600.10, \$267.24 and \$255.42, respectively. As of December 31, 2021, we expect to recognize \$116.8 million of total unamortized compensation costs, net of estimated forfeitures, related to RSUs over a weighted average period of 2.1 years.

Market-Performance Based Restricted Stock Units

We grant MSUs to our executive officers. Each MSU represents the right to one share of Align's common stock. The actual number of MSUs which will be eligible to vest will be based on the performance of Align's 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 of eligible to vest in the future is 250% of the MSUs initially granted.

The following table summarizes the MSU performance for the year ended December 31, 2021:

	Number of Shares Underlying MSUs (in thousands)	Weighted A		Weighted Average Remaining Contractual Term (in years)	Aggregate trinsic Value n thousands)
Unvested as of December 31, 2020	227	\$	430.50		
Granted ¹	177		658.02		
Vested and released	(230)		513.73		
Unvested as of December 31, 2021	174	\$	551.57	1.0	\$ 114,414

¹ Includes MSUs vested during the period above 100% of the grant as actual shares released is based on Align's stock performance over the vesting period

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (calculated by multiplying our closing stock price on the last trading day of 2021 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 2021. This amount will fluctuate based on the fair market value of our stock. During 2021, of the 229,877 shares vested and released, 104,317 shares were withheld for employee statutory tax obligations, resulting in a net issuance of 125,560 shares.

The total fair value of MSUs vested as of their respective vesting dates during 2021, 2020 and 2019 was \$135.6 million, \$47.1 million and \$47.7 million, respectively. As of December 31, 2021, we expect to recognize \$38.5 million of total unamortized compensation costs, net of estimated forfeitures, related to MSUs over a weighted average period of 1.0 year.

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

	Year Ended December 31,							
	 2021	2020		2019				
Expected term (in years)	3.0		3.0		3.0			
Expected volatility	56.3 %		44.4 %		37.3 %			
Risk-free interest rate	0.2 %		1.4 %		2.5 %			
Expected dividends	_		_		_			
Weighted average fair value per share at grant date	\$ 1,102.09	\$	392.67	\$	392.03			

Employee Stock Purchase Plan ("ESPP")

In May 2010, our stockholders approved the 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan") which consists of consecutive overlapping twenty-four month offering periods with four six-month purchase periods in each offering period. Employees purchase shares at 85% of the lower of the fair market value of the common stock at either the beginning of the offering period or the end of the purchase period. The 2010 Purchase Plan will continue until terminated by either the Board of Directors or its administrator. In June 2019, the 2010 Purchase Plan was amended to include a non-Code Section 423 component to grant 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,						
	2021 2020				2019			
Number of shares issued (in thousands)		131	116		130			
Weighted average price	\$	195.44	\$ 175.69	\$	136.73			

As of December 31, 2021, 2,194,566 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,						
	202	21	2020	2019				
Expected term (in years)		1.1	1.0	1.4				
Expected volatility		52.7 %	55.0 %	50.0 %				
Risk-free interest rate		0.1 %	0.9 %	2.2 %				
Expected dividends		_	_	_				
Weighted average fair value at grant date	\$	246.84 \$	96.94 \$	86.02				

We recognized stock-based compensation related to our employee stock purchase plan of \$12.2 million, \$10.5 million and \$12.1 million for the year ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we expect to recognize \$10.4 million of total unamortized compensation costs related to future employee stock purchases over a weighted average period of 0.5 year.

Note 13. Common Stock Repurchase Programs

In May 2018, our Board of Directors authorized a plan to repurchase up to \$600.0 million of our common stock ("May 2018 Repurchase Program"). As of December 31, 2021, the authorization under the May 2018 Repurchase Program was completed. In May 2021, our Board of Directors authorized a plan to repurchase up to \$1.0 billion of our common stock ("May 2021 Repurchase Program"). As of December 31, 2021, we have \$725.0 million available for repurchase under the May 2021 Repurchase Program.

Accelerated Stock Repurchase Agreements ("ASRs")

We entered into the following 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. The following table summarizes the information regarding repurchases of our common stock under ASRs:

Agreement Date	Repurchase Program	mount Paid in millions)	Completion Date	Total Shares Received	Av	verage Price per Share
Q3 2019	May 2018	\$ 200.0	Q3 2019	1,132,464	\$	176.61
Q2 2021	May 2018	\$ 100.0	Q3 2021	171,322	\$	583.70
Q2 2021	May 2021	\$ 100.0	Q3 2021	161,707	\$	618.40
Q3 2021	May 2021	\$ 75.0	Q3 2021	109,239	\$	686.91
Q4 2021	May 2021	\$ 100.0	Q4 2021	150,031	\$	666.53

Open Market Common Stock Repurchases

During the year ended December 31, 2019, we repurchased on the open market approximately 0.8 million shares of our common stock at an average price of \$264.93 per share, including commissions, for an aggregate purchase price of \$200.0 million.

Subsequent to year end, during February 2022, we repurchased on the open market approximately 0.1 million shares of our common stock at an average price of \$522.35 per share, including commissions, for an aggregate purchase price of \$75.0 million.

Note 14. Employee Benefit Plans

We have defined contribution retirement plan under Section 401(k) of the Internal Revenue Code for our U.S. employees which covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. We match 50% of our employee's salary deferral contributions up to 6% of the employee's eligible compensation. We contributed approximately \$8.5 million, \$6.9 million and \$6.2 million to the 401(k) plan during the year ended December 31, 2021, 2020 and 2019, respectively. We also have defined contribution retirement plans outside of the U.S. to which we contributed \$42.3 million, \$28.9 million and \$25.4 million during the year ended December 31, 2021, 2020 and 2019, respectively.

Note 15. Income Taxes

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

	Year Ended December 31,					
		2021		2020		2019
Domestic	\$	378,478	\$	173,099	\$	184,956
Foreign		633,945		205,850		377,695
Net income before provision for (benefit from) income taxes and equity in losses of investee	\$	1,012,423	\$	378,949	\$	562,651

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

	Year Ended December 31,					
		2021		2020		2019
Federal	'					
Current	\$	157,383	\$	55,291	\$	76,528
Deferred		(25,598)		(11,749)		1,235
		131,785		43,542		77,763
State	'					
Current		28,365		8,862		9,169
Deferred		(5,860)		(2,121)		209
		22,505		6,741		9,378
Foreign						
Current		42,681		29,399		28,364
Deferred		43,432		(1,476,621)		(3,158)
		86,113		(1,447,222)	•	25,206
Provision for (benefit from) income taxes	\$	240,403	\$	(1,396,939)	\$	112,347

The differences between income taxes using the federal statutory income tax rate for 2021, 2020 and 2019 and our effective tax rates are as follows:

	Year Ended December 31,				
	2021	2020	2019		
U.S. federal statutory income tax rate	21.0 %	21.0 %	21.0 %		
State income taxes, net of federal tax benefit	2.2	1.8	1.7		
U.S. tax on foreign earnings	2.7	_	1.9		
Impact of differences in foreign tax rates	(2.0)	5.6	(5.1)		
Stock-based compensation	(0.3)	1.1	(0.3)		
Impact of expiration of statute of limitations	(0.7)	(0.3)	_		
Impact of intra-entity intellectual property rights transfer	_	(395.6)	_		
Settlement on audits	_	(1.4)	_		
Impact of U.S. Tax Cuts and Jobs Act	_	(0.5)	_		
Change in valuation allowance	1.1	0.1	0.1		
Other items not individually material	(0.3)	(0.4)	0.7		
Effective tax rate	23.7 %	(368.6)%	20.0 %		

As of December 31, 2021, substantially all of the earnings previously determined to be not indefinitely reinvested have been repatriated. U.S. income taxes have already been provided on the \$1,257.5 million undistributed earnings that is indefinitely reinvested in our international operations, therefore, the tax impact upon distribution is limited to mainly state income and withholding taxes and is not significant.

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

As of December 31, 2021 and 2020, the significant components of our deferred tax assets and liabilities are (in thousands):

	December 31,			
	2021		2020	
Deferred tax assets:				
Net operating loss and capital loss carryforwards	\$ 11,069	\$	20,728	
Reserves and accruals	47,641		34,469	
Stock-based compensation	13,576		10,842	
Deferred revenue	83,514		32,562	
Amortizable tax basis in intangibles	1,392,471		1,468,159	
Net translation losses	10,008		2,939	
Credit carryforwards	5,637		905	
Total deferred tax assets	1,563,916		1,570,604	
Deferred tax liabilities:				
Depreciation and amortization	11,915		14,730	
Acquisition-related intangibles	28,989		35,689	
Prepaid expenses	6,931		1,720	
Total deferred tax liabilities	 47,835		52,139	
Net deferred tax assets before valuation allowance	 1,516,081		1,518,465	
Valuation allowance	(12,938)		(1,325)	
Net deferred tax assets	\$ 1,503,143	\$	1,517,140	

The available positive evidence at December 31, 2021 included historical operating profits and a projection of future income sufficient to realize most of our remaining deferred tax assets. As of December 31, 2021, it was considered more likely than not that our deferred tax assets would be realized with the exception of certain net operating loss, capital loss carryovers and unrealized translation losses as we are unable to forecast sufficient future profits to realize the deferred tax assets. The total valuation allowance as of December 31, 2021 was \$12.9 million. During the year ended December 31, 2021, the valuation allowance increased by \$11.6 million primarily due to deferred tax assets related to unrealized translation losses and net operating loss from one of our German subsidiaries that are not more likely than not to be realized.

As of December 31, 2021, we have foreign net operating loss carryforwards of approximately \$44.8 million, attributed mainly to losses in Israel, China and Germany. The losses in Israel and Germany can be carried forward indefinitely. The operating loss carryforwards in China, if not utilized, will expire beginning 2026.

The changes in the balance of gross unrecognized tax benefits, which exclude interest and penalties, for the year ended December 31, 2021, 2020 and 2019, are as follows (in thousands):

	Year Ended December 31,						
		2021		2020		2019	
Gross unrecognized tax benefits at January 1,	\$	46,320	\$	46,650	\$	33,262	
Increases related to tax positions taken during the current year		27,710		20,592		19,012	
Increases related to tax positions taken during a prior year		5,471		10,201		143	
Decreases related to tax positions taken during a prior year		(5,804)		(29,977)		(3,783)	
Decreases related to expiration of statute of limitations		(8,986)		_		(1,984)	
Decreases related to settlement with tax authorities		(1,416)		(1,146)		_	
Gross unrecognized tax benefits at December 31,	\$	63,295	\$	46,320	\$	46,650	

The total amount of gross unrecognized tax benefits as of December 31, 2021 was \$63.3 million, of which \$61.9 million would impact our effective tax rate if recognized.

We file U.S. federal, U.S. state, and non-U.S. income tax returns. Our major tax jurisdictions include U.S. federal, the State of California and Switzerland. For U.S. federal and state tax returns, we are no longer subject to tax examinations for years before 2018 and 2014, respectively. Our Israeli subsidiary is under tax audit for years 2016 through 2019. During the fourth quarter of 2021, the Israel Tax Authority issued a tax assessment in connection with a 2016 transaction to which our Israeli subsidiary was a party. We intend to file an administrative appeal during the first quarter of 2022 and will continue to

vigorously defend our Israeli subsidiary's tax return position. Based on our assessment of the information currently available, we have not derecognized or remeasured our tax positions with respect to this matter during the year. With few exceptions, we are no longer subject to examination by foreign tax authorities for years before 2014.

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, 2021, 2020 and 2019 as well as accrued as of December 31, 2021 and 2020 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 16. 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 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,					
	2021	2020	2019			
Numerator:						
Net income	\$ 772,020	\$ 1,775,888	\$ 442,776			
Denominator:						
Weighted average common shares outstanding, basic	78,917	78,760	79,424			
Dilutive effect of potential common stock	753	470	676			
Total shares, diluted	79,670	79,230	80,100			
Net income per share, basic	\$ 9.78	\$ 22.55	\$ 5.57			
Net income per share, diluted	\$ 9.69	\$ 22.41	\$ 5.53			
Anti-dilutive potential common shares 1	1	280	79			

¹ Represents RSUs and MSUs not included in the calculation of diluted net income per share as the effect would have been anti-dilutive.

Note 17. Supplemental Cash Flow Information

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

	Year Ended December 31,					
	2021		2020		2019	
Taxes paid	\$ 203,309	\$	76,332	\$	71,746	
Non-cash investing and financing activities:						
Acquisition of property, plant and equipment in accounts payable and accrued liabilities	\$ 64,135	\$	37,267	\$	16,488	
Issuance of promissory note in exchange for sale of equity method investment	\$ _	\$	_	\$	54,154	
Cash paid for amounts included in the measurement of lease liabilities:						
Operating cash flows from operating leases	\$ 29,769	\$	26,022	\$	26,337	
Investing cash flows from finance leases (1)	\$ _	\$	_	\$	10,896	
Financing cash flows from finance leases	\$ _	\$	_	\$	45,773	
Right-of-use assets obtained in exchange for lease obligations:						
Operating leases	\$ 68,463	\$	47,981	\$	32,723	
Finance leases	\$ _	\$	_	\$	51,064	

w Ended December 21

Note 18. Segments and Geographical Information

Segment Information

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

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

- Our Clear Aligner segment consists of Comprehensive Products, Non-Comprehensive Products and Non-Case revenues as defined below:
 - · Comprehensive Products include, but are not limited to, Invisalign Comprehensive and Invisalign First.
 - Non-Comprehensive Products include, but are not limited to, Invisalign Moderate, Lite and Express packages and Invisalign Go and Invisalign Go Plus.
 - Non-Case products include, but are not limited to, retention products, Invisalign training, adjusting tools used by dental professionals during the course of treatment and Consumer Products that are complementary to our doctor-prescribed principal products, such as aligner cases (clamshells), teeth whitening products, cleaning solutions (crystals, foam and other material) and other oral health products available in certain e-commerce channels in the U.S.
- Our Systems and Services segment consists of our iTero intraoral scanning systems, which includes a single hardware platform and restorative or
 orthodontic software options. Our services include subscription software, disposables, rentals, pay per scan services, as well as exocad's
 CAD/CAM software solutions that integrate workflows to dental labs and dental practices.

¹ A portion of finance lease purchase payment relates to leasing a part of the building to a third party as a lessor. This amount is included in Other Investing Activities in our Consolidated Statement of Cash Flows.

, G	ŕ	Year Ended December 31,					
		2021		2020		2019	
Net revenues							
Clear Aligner	\$	3,247,080	\$	2,101,459	\$	2,025,750	
Systems and Services		705,504		370,482		381,046	
Total net revenues	\$	3,952,584	\$	2,471,941	\$	2,406,796	
Gross profit							
Clear Aligner	\$	2,474,373	\$	1,532,130	\$	1,499,713	
Systems and Services		460,982		231,105		244,184	
Total gross profit	\$	2,935,355	\$	1,763,235	\$	1,743,897	
Income from operations							
Clear Aligner	\$	1,325,866	\$	768,045	\$	835,957	
Systems and Services		259,127		96,052		137,720	
Unallocated corporate expenses		(608,593)		(476,926)		(431,184)	
Total income from operations	\$	976,400	\$	387,171	\$	542,493	
Stock-based compensation							
Clear Aligner	\$	10,648	\$	8,975	\$	9,220	
Systems and Services		705		734		255	
Unallocated corporate expenses		102,983		88,718		78,709	
Total stock-based compensation	\$	114,336	\$	98,427	\$	88,184	
Depreciation and amortization							
Clear Aligner	\$	50,723	\$	41,371	\$	38,979	
Systems and Services		21,581		16,798		7,441	
Unallocated corporate expenses		36,425		35,369		32,570	
Total depreciation and amortization	\$	108,729	\$	93,538	\$	78,990	
Impairments and other charges (gains), net							
Clear Aligner	\$	_	\$	_	\$	22,990	
Total impairments and other charges (gains), net	\$	_	\$		\$	22,990	
Litigation settlement gain							
Clear Aligner	\$		\$		\$	(51,000)	
Total litigation settlement gain	\$		\$		\$	(51,000)	

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

	Year Ended December 31,						
		2021		2020		2019	
Total segment income from operations	\$	1,584,993	\$	864,097	\$	973,677	
Unallocated corporate expenses		(608,593)		(476,926)		(431,184)	
Total income from operations		976,400		387,171		542,493	
Interest income	·	3,103		3,125		12,482	
Other income (expense), net		32,920		(11,347)		7,676	
Net income before provision for (benefit from) income taxes and equity in losses of investee	\$	1,012,423	\$	378,949	\$	562,651	

Geographical Information

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

	fear Ended December 31,						
	2021		2020		2019		
Net revenues 1:							
U.S.	\$ 1,724,296	\$	1,099,564	\$	1,161,959		
Switzerland ²	1,353,229		809,080		_		
China	275,503		199,851		196,733		
The Netherlands ²	_		_		760,444		
Other International	599,556		363,446		287,660		
Total net revenues	\$ 3,952,584	\$	2,471,941	\$	2,406,796		

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

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

	As of December 31,			
	2021	2020		
Long-lived assets ¹ :	 			
Switzerland	\$ 444,205	\$ 257,333		
U.S.	210,582	180,539		
China	125,346	113,918		
Costa Rica	92,204	97,804		
Other International	330,846	167,670		
Total long-lived assets	\$ 1,203,183	\$ 817,274		
		-		

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

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

None

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of December 31, 2021 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

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

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

Changes in internal control over financial reporting.

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In 2020, we implemented a new international corporate structure. This changed the structure of international procurement and sales operations from the Netherlands to Switzerland.

Item 9B. Other Information.

None.

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

None.

PART III

Certain information required by Part III is omitted from this Form 10-K because we intend to file a definitive Proxy Statement for our 2022 Annual Meeting of Stockholders (the "Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included therein is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

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

Code of Ethics

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

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

Item 11. Executive Compensation.

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

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

The information required by Item 403 of Regulation S-K is incorporated by reference to the Proxy Statement under the section captioned "Principal Stockholders".

Equity Compensation Plan Information

The following table provides information as of December 31, 2021 about our common stock that may be issued upon the awards granted to employees, consultants or members of our Board of Directors under all existing equity compensation plans, including the 2005 Incentive Plan and the Employee Stock Purchase Plan ("ESPP"), each as amended, and certain individual arrangements (Refer to *Note 12 "Stockholders' Equity" of the Notes to Consolidated Financial Statements* for a description of our equity compensation plans).

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units (a)	Veighted average exercise price of standing options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	665,957 1	\$ _	6,439,289	2, 3
Equity compensation plans not approved by security holders	_	_	_	
Total	665,957	\$ _	6,439,289	

¹ Includes 491,858 RSUs and 174,099 MSUs at target

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

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

Item 14. Principal Accountant Fees and Services.

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

² Includes 2,194,566 shares available for issuance under our ESPP. We are unable to ascertain with specificity the number of securities to be issued upon exercise of outstanding rights or the weighted average exercise price of outstanding rights under the ESPP.

Includes additional 496,182 of potentially issuable MSUs above target if performance targets are achieved at maximum payout (counted one and nine-tenths (1 9/10) shares for every one (1) issuable share against the authorized share reserve)

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	56
Consolidated Statements of Operations for the year ended December 31, 2021, 2020 and 2019	58
Consolidated Statements of Comprehensive Income for the year ended December 31, 2021, 2020 and 2019	59
Consolidated Balance Sheets as of December 31, 2021 and 2020	60
Consolidated Statements of Stockholders' Equity for the year ended December 31, 2021, 2020 and 2019	<u>61</u>
Consolidated Statements of Cash Flows for the year ended December 31, 2021, 2020 and 2019	62
Notes to Consolidated Financial Statements	63

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, 2021, 2020 and 2019

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
		<u> </u>		(in tho	usano	ls)	
P	Allowance for doubtful accounts:						
	Year Ended December 31, 2019	\$	2,378	\$ 5,853	\$	(1,475)	\$ 6,756
	Year Ended December 31, 2020	\$	6,756	\$ 12,073	\$	(8,590)	\$ 10,239
	Year Ended December 31, 2021	\$	10,239	\$ 2,814	\$	(3,808)	\$ 9,245
V	Valuation allowance for deferred tax assets:						
	Year Ended December 31, 2019	\$	251	\$ 835	\$	_	\$ 1,086
	Year Ended December 31, 2020	\$	1,086	\$ 239	\$	_	\$ 1,325
	Year Ended December 31, 2021	\$	1,325	\$ 11,613	\$	_	\$ 12,938

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

Exhibit Number	Description	Form	Date	Number Incorporated by Reference herein	Filed herewith
<u>3.1</u>	Amended and Restated Certificate of Incorporation of registrant	S-1, as amended (File No. 333-49932)	12/28/2000	3.1	
<u>3.1A</u>	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	5/20/2016	3.01	
<u>3.2</u>	Amended and Restated Bylaws of registrant	8-K	2/29/2012	3.2	
3.2A	Amendment to Amended and Restated Bylaws of registrant	Def 14A	4/7/2021	1.0	
<u>4.1</u>	Form of Specimen Common Stock Certificate	S-1, as amended (File No. 333-49932)	1/17/2001	4.1	
<u>4.2</u>	Description of the Capital Stock of registrant	10-K	2/28/2020	4.2	
10.1A†	Amended Registrant's 2010 Employee Stock Purchase Plan	Def 14A	4/7/2021	2.0	
10.2†	Registrant's 2005 Incentive Plan (as amended May 2016)	10-K	2/26/2021	10.2	
<u>10.3†</u>	Form of RSU agreement under Registrant's 2005 Incentive Plan (Officer Form for officers appointed after September 2016)	10-K	2/28/2020	10.3	
<u>10.3A†</u>	Form of RSU agreement under Registrant's 2005 Incentive Plan (Officer Form for officers appointed prior to September 2016)	10-K	2/28/2020	10.3A	
<u>10.4†</u>	Form of RSU agreement (CEO)	10-K	2/28/2020	10.4	
<u>10.5†</u>	Form of RSU agreement under Registrant's 2005 Incentive Plan (Non-employee Director Form)	10-K	2/28/2020	10.5	
<u>10.6†</u>	Align 2019 Global RSU Agreement	10-K	2/28/2019	10.6	
<u>10.7†</u>	Form of option award agreement under registrant's 2005 Incentive Plan	10-Q	8/4/2005	10.4	
<u>10.8†</u>	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2018, 2019 and 2020 to officers appointed after September 2016)	10-K	2/28/2020	10.8	
<u>10.8A†</u>	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2018, 2019 and 2020 to officers appointed prior to September 2016)	10-K	2/28/2020	10.8A	
<u>10.9†</u>	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2021 to officers appointed after September 2016)	10-K	2/26/2021	10.9	
<u>10.9A†</u>	Form of Market Stock Unit Agreement under Registrant's 2005 Incentive Plan (Officer Form for MSU awards granted in 2021 to officers appointed prior to September 2016)	10-K	2/26/2021	10.9A	
<u>10.10†</u>	Form of Market Stock Unit Agreement for CEO (Focal grants)	10-K	2/28/2020	10.9	
<u>10.11†</u>	Form of Market Stock Unit Agreement for CEO Special MSU Award June 2018	8-K	6/25/2018	10.1	
<u>10.12†</u>	Form of Employment Agreement entered into by and between registrant and each executive officer (other than CEO for executives appointed prior to September 2016)	10-Q	5/8/2008	10.3	
<u>10.13†</u>	Form of Employment Agreement entered into by and between registrant and each executive officer (other than CEO for executives appointed after September 2016)	10-K	2/28/2017	10.8	
<u>10.14†</u>	Amended and Restated Chief Executive Officer Employment Agreement between Align Technology, Inc. and Joseph Hogan	10-Q	5/1/2015	10.30	
<u>10.15†</u>	Employment Agreement between registrant and John F. Morici (Chief Financial Officer)	10-Q	11/8/2016	10.2	
<u>10.16†</u>	Form of Indemnification Agreement by and between registrant and its Board of Directors and its executive officers	No. 333-49932)	1/17/2001	10.15	
<u>10.17</u>	Sale and Purchase Agreement between CETP III Ivory S.a.r.l., and Align Technology, Inc. and its indirect wholly owned German subsidiary, mertus 602.GmbH, dated March 3, 2020	10-Q	5/5/2020	10.1	

Exhibit

Exhibit Number	Description	Form	Date	Number Incorporated by Reference herein	Filed herewith
<u>10.18</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	10-Q	10/30/2020	10.1	
<u>10.19</u>	Fixed Dollar Accelerated Share Repurchase Transaction dated October 29, 2021				*
<u>21.1</u>	Subsidiaries of Align Technology, Inc.				*
<u>23.1</u>	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm				*
<u>31.1</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>31.2</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>32t</u>	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003				*
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).				*
101.SCH	Inline XBRL Taxonomy Extension Schema Document				*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				*

Exhibit

Item 16. Form 10-K Summary.

Not applicable.

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.

t Furnished herewith

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.

Joseph M. Hogan	
President and Chief Executive Officer Date: February 25, 2022	

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/S/ JOSEPH M. HOGAN	President and Chief Executive Officer (Principal Executive Officer)	February 25, 2022
Joseph M. Hogan	Executive Officer)	
/S/ JOHN F. MORICI	Chief Financial Officer and Executive Vice	February 25, 2022
John F. Morici	 President, Global Finance (Principal Financial Officer and Principal Accounting Officer) 	
/S/ KEVIN J. DALLAS	Director	February 25, 2022
Kevin J. Dallas		
/S/ JOSEPH LACOB	Director	February 25, 2022
Joseph Lacob		
/S/ C. RAYMOND LARKIN, JR.	Director	February 25, 2022
C. Raymond Larkin, Jr.		
/S/ GEORGE J. MORROW	Director	February 25, 2022
George J. Morrow		
/S/ ANNE M. MYONG	Director	February 25, 2022
Anne M. Myong		
/S/ ANDREA L. SAIA	Director	February 25, 2022
Andrea L. Saia		
/S/ GREG J. SANTORA	Director	February 25, 2022
Greg J. Santora		
/S/ SUSAN E. SIEGEL	Director	February 25, 2022
Susan E. Siegel		
/S/ WARREN S. THALER	Director —	February 25, 2022
Warren S. Thaler		

Citibank, N.A. 388 Greenwich Street, 4th Floor

New York, NY 10013 Attention: Equity Derivatives

Opening Transaction

To: Align Technology, Inc.

410 N. Scottsdale Road, Suite 1300

Tempe, Arizona 85281

A/C:

Citibank, N.A.

From:

Fixed Dollar Accelerated Share Repurchase Transaction

Re:

Date: October 29, 2021

Dear Sir/Madam:

The purpose of this letter agreement (this "Confirmation") is to confirm the terms and conditions of the Transaction entered into between Citibank, N.A. ("Dealer") and Align Technology, Inc. ("Issuer") on the Trade Date specified below (the "Transaction"). This confirmation constitutes a "Confirmation" as referred to in the Agreement specified below.

The definitions and provisions contained in the 2002 ISDA Equity Derivatives Definitions (as published by the International Swaps and Derivatives Association, Inc. ("ISDA")) (the "Equity Definitions") are incorporated into this Confirmation. The Transaction is a Share Forward Transaction for purposes of the Equity Definitions. Any reference to a currency shall have the meaning contained in Section 1.7 of the 2006 ISDA Definitions, as published by ISDA.

1. This Confirmation evidences a complete and binding agreement between Dealer and Issuer as to the terms of the Transaction to which this Confirmation relates and shall supersede all prior or contemporaneous written or oral communications with respect thereto. This Confirmation shall be subject to an agreement (the "Agreement") in the form of the 2002 ISDA Master Agreement as if Dealer and Issuer had executed an agreement in such form without any Schedule but with the elections set forth in this Confirmation (and (1) the election of USD as the Termination Currency, (2) the election that subparagraph (ii) of Section 2(c) will not apply to the Transactions and (3) the election that the "Cross Default" provisions of Section 5(a)(vi) shall apply to Dealer, with a "Threshold Amount" of 3% of Dealer shareholders' equity for Dealer (provided that (a) the phrase "or becoming capable at such time of being declared" shall be deleted from clause (1) of such Section 5(a)(vi) of the Agreement and (b) the following sentence shall be added to the end thereof: "Notwithstanding the foregoing, a default hereunder shall not constitute an Event of Default if (i) the default was caused solely by error or omission of an administrative or operational nature; (ii) funds were available to enable the party to make the payment when due; and (iii) the payment is made within two Local Business Days of such party's receipt of written notice of its failure to pay)".

The Transaction shall be the only transaction under the Agreement. If there exists any ISDA Master Agreement between Dealer and Issuer or any confirmation or other agreement between Dealer and Issuer pursuant to which an ISDA Master Agreement is deemed to exist between Dealer and Issuer, then, notwithstanding anything to the contrary in such ISDA Master Agreement, such confirmation or agreement or any other agreement to which Dealer and Issuer are parties, the Transaction shall not be considered a transaction under, or otherwise governed by, such existing or deemed to be existing ISDA Master Agreement.

If there is any inconsistency between the Agreement, this Confirmation and the Equity Definitions, the following will prevail for purposes of the Transaction in the order of precedence indicated: (i) this Master Confirmation; (ii) the Equity Definitions; and (iii) the Agreement.

2. The terms of the particular Transaction to which this Confirmation relates are as follows:

GENERAL TERMS:

Trade Date: As specified in Schedule I

Buyer: Issuer Seller: Dealer

Shares: Common Stock, par value USD 0.0001 per share, of Issuer (Ticker: ALGN)

Forward Price: A price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent) equal to the greatest statement of the price per Share (as determined by the Calculation Agent).

A price per Share (as determined by the Calculation Agent) equal to the greater of (A) (i) the arithmetic mean (not a weighted average, subject to "Market Disruption Event" below) of the 10b-18 VWAP on each Observation Date that is a Trading Day during the Calculation Period minus (ii) the Discount and (B) \$5.00.

Discount: 10b-18 VWAP:

As specified in Schedule I

On any Trading Day, a price per Share equal to the volume- weighted average price of the Rule 10b-18 eligible trades in the Shares for the entirety of such Trading Day as determined by the Calculation Agent by reference to the screen entitled "ALGN <Equity> AQR SEC" or any successor page as reported by Bloomberg L.P. or any successor (excluding (i) trades that do not settle regular way, (ii) opening (regular way) reported trades in the consolidated system on such Scheduled Trading Day (including, for the avoidance of doubt, the first reported trade on the Exchange following the scheduled open of trading on the Exchange), (iii) trades that occur in the last ten minutes before the scheduled close of trading on the Exchange on such Scheduled Trading Day and ten minutes before the scheduled close of the primary trading in the market where the trade is effected, and (iv) trades on such Scheduled Trading Day that do not satisfy the requirements of Rule 10b-18(b)(3) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") on such Trading Day) or, if the price displayed on such screen is clearly erroneous, as determined by the Calculation Agent in good faith and in a commercially reasonable manner.

Observation Dates: Calculation Period:

As specified in Schedule I

The period from, and including, the first Observation Date that is a Trading Day that occurs on or after the Prepayment Date to, but excluding, the relevant Valuation Date; <u>provided</u>, <u>however</u>, that if the Valuation Date is the Scheduled Valuation Date, then the Valuation Date shall be included in the Calculation Period; <u>provided further</u> that in no event shall any Scheduled Valuation Date be postponed to a date later than the Final Termination Date.

Final Termination Date:

As specified in Schedule I; <u>provided</u> that if a Market Disruption Event has occurred pursuant to Section 7 of this Confirmation, such Final Termination Date shall be postponed by one Trading Day for every Trading Day that is a Disrupted Day as a result of such Merger Transaction during the Calculation Period

Trading Day: Initial Shares:

Any Exchange Business Day that is not a Disrupted Day in whole

As specified in Schedule I; <u>provided</u> that if Dealer is unable to borrow or otherwise acquire a number of Shares equal to the Initial Shares for delivery to Issuer on the Initial Share Delivery Date, the Initial Shares delivered on the Initial Share Delivery Date shall be reduced to such number of Shares that Dealer is able to so borrow or otherwise acquire, and thereafter Dealer shall continue to use commercially reasonable efforts to borrow or otherwise acquire a number of Shares, at a stock borrow cost no greater than the Initial Stock Loan Rate, equal to the shortfall in the Initial Shares and to deliver such additional Shares as soon as reasonably practicable. For the avoidance of doubt, the aggregate of all shares delivered to Dealer in respect of the Transaction pursuant to this paragraph shall be the "Initial Shares" for purposes of determining the "Settlement Amount" below.

Initial Share Delivery Date:

One Exchange Business Day following the Trade Date. On the Initial Share Delivery Date, Seller shall deliver to Buyer a number of Shares equal to the Initial Shares in accordance with Section 9.4 of the Equity Definitions, with the Initial Share Delivery Date being deemed to be a "Settlement Date" for purposes of such Section 9.4.

Prepayment:

Applicable

Prepayment Amount:

As specified in Schedule I One Exchange Business Day following the Trade Date. On the Prepayment Date, Buyer shall pay to Seller the Prepayment Amount.

Prepayment Date:

Exchange:

The Nasdaq Global Select Market

Related Exchange:

All Exchanges; <u>provided</u> that Section 1.26 of the Equity Definitions shall be amended to add the words "United States" before the word "exchange" in the tenth line of such Section.

Market Disruption Event:

The definition of "Market Disruption Event" in Section 6.3(a) of the Equity Definitions is hereby amended by deleting the words "at any time during the one-hour period that ends at the relevant Valuation Time, Latest Exercise Time, Knock-in Valuation Time or Knock-out Valuation Time, as the case may be," starting in the third line thereof.

Section 6.3(d) of the Equity Definitions is hereby amended by deleting the remainder of the provision following the term "Scheduled Closing Time" in the fourth line thereof.

Notwithstanding anything to the contrary in the Equity Definitions, if any Exchange Business Day in the Calculation Period or the Buyer Settlement Valuation Period is a Disrupted Day, the Calculation Agent shall have the option, in its reasonable discretion, to take one or more of the following actions in a good faith and commercially reasonable manner: (i) determine that such Exchange Business Day is a Disrupted Day in part, in which case the Calculation Agent shall (x) determine the 10b-18 VWAP on such Exchange Business Day based on Rule 10b-18 eligible trades in the Shares on such day taking into account the nature and duration of the relevant Market Disruption Event and (y) determine the Forward Price or Buyer Settlement Price, as applicable, using an appropriately weighted average of 10b-18 VWAPs instead of an arithmetic mean, and/or (ii) elect to (x) postpone the Scheduled Valuation Date (in the case of a Disrupted Day during the Calculation Period) or (y) extend the Buyer Settlement Valuation Period (in the case of a Disrupted Day during the Buyer Settlement Valuation Period or Buyer Settlement Valuation Period, as applicable; provided that in no event shall any Scheduled Valuation Date be postponed to a date later than the Final Termination Date. For the avoidance of doubt, if the Calculation Agent takes the action described in clause (i) above, then such Disrupted Day shall be a Trading Day for purposes of calculating the Forward Price or Buyer Settlement Price, as applicable.

Any Exchange Business Day on which, as of the date hereof, the Exchange is scheduled to close prior to its normal close of trading shall be deemed not to be an Exchange Business Day; if a closure of the Exchange prior to its normal close of trading on any Exchange Business Day is scheduled following the date hereof, then such Exchange Business Day shall be deemed to be a Disrupted Day in full.

If a Disrupted Day occurs during the Calculation Period or the Buyer Settlement Valuation Period and each of the nine immediately following Scheduled Trading Days is a Disrupted Day, then the Calculation Agent may, in its good faith and commercially reasonable discretion, deem such ninth Scheduled Trading Day to be an Exchange Business Day that is not a Disrupted Day and determine the 10b-18 VWAP for such ninth Scheduled Trading Day using its good faith and commercially reasonable estimate of the value of the Shares on such ninth Scheduled Trading Day based on the volume, historical trading patterns and trading price of the Shares.

VALUATION:

Valuation Date:

The earlier of (i) the Scheduled Valuation Date and (ii) any earlier accelerated Valuation Date as a result of Dealer's election in accordance with the immediately succeeding paragraph.

Dealer shall have the right, in its absolute discretion but subject to the limitation set forth in the immediately succeeding paragraph, to accelerate the Valuation Date, in whole or in part (an "Acceleration"), to any Exchange Business Day that is on or after the Lock-Out Date and prior to the Scheduled Valuation Date by notice (each such notice, an "Acceleration Notice") to Issuer by 9:00 p.m., New York City time, on the Exchange Business Day immediately following the accelerated Valuation Date; provided that if at any time after the Lock-Out Date Dealer expects the Settlement Amount to be a negative number, then Dealer shall provide Issuer notice of any such expectation.

Dealer shall specify in each Acceleration Notice the portion of the Prepayment Amount that is subject to acceleration (which may be less than the full Prepayment Amount, but only so long as such portion is not less than USD 25,000,000). If the portion of the Prepayment Amount that is subject to acceleration is less than the full Prepayment Amount, then the Calculation Agent shall adjust the terms of the Transaction as appropriate in order to take into account the occurrence of such accelerated Valuation Date (including cumulative adjustments to take into account all prior accelerated Valuation Dates).

On each Valuation Date, the Calculation Agent shall calculate the Settlement Amount.

As specified in Schedule I, subject to postponement in accordance with "Market Disruption Event" above

As specified in Schedule I

Applicable.

On the Settlement Date, Seller shall deliver to Buyer a number of Shares equal to (a) (i) the Prepayment Amount <u>divided by</u> (ii) the Forward Price <u>minus</u> (b) the Initial Shares (such number of Shares, the "Settlement Amount"), rounded to the nearest whole number of Shares; <u>provided</u>, <u>however</u>, that if the Settlement Amount is less than zero, then the Buyer Settlement Provisions in Annex A hereto shall apply.

USD

The date that falls one Settlement Cycle after the relevant Valuation Date.

The last sentence of Section 9.2, Sections 9.8, 9.9, 9.10 and 9.11 (except that the Representation and Agreement contained in Section 9.11 of the Equity Definitions shall be modified by excluding any representations therein relating to restrictions, obligations, limitations or requirements under applicable securities laws arising as a result of the fact that Buyer is the issuer of the Shares) and Section 9.12 of the Equity Definitions will be applicable to the Transaction.

Notwithstanding anything to the contrary in Section 11.2(e) of the Equity Definitions, an Extraordinary Dividend shall not constitute a Potential Adjustment Event.

It shall constitute a Potential Adjustment Event if a Disrupted Day occurs or, pursuant to Section 9 below, is deemed to occur (in whole or in part) on any Trading Day on or prior to the Valuation Date.

Any dividend or distribution on the Shares with an ex-dividend date occurring during the period from, and including, the Trade Date to, and including, the last day of the Potential Purchase Period (as defined below) (other than any dividend or distribution of the type described in Section 11.2(e) (i), Section 11.2(e)(ii)(A) or Section 11.2(e)(ii)(B) of the Equity Definitions).

Scheduled Valuation Date:

Lock-Out Date:

SETTLEMENT TERMS:

 $Physical\ Settlement:$

Settlement Currency: Settlement Date: Other Applicable Provisions:

SHARE ADJUSTMENTS:

Potential Adjustment Event:

Extraordinary Dividend:

Method of Adjustment:

Calculation Agent Adjustment; <u>provided</u> that the parties hereto agree that any Share repurchases by the Issuer, whether pursuant to Rule 10b-18 of the Exchange Act, Rule 10b5-1 of the Exchange Act on customary terms, at prevailing market prices, or VWAP (subject to any discounts thereto) shall not be considered Potential Adjustment Events; provided further that adjustments for any Potential Adjustment Event (other than pursuant to any Potential Adjustment Event defined in Sections 11.2(e)(i), 11.2(e)(ii)(A) and 11.2(e)(iii) of the Equity Definitions) may be made to account for changes in volatility, stock loan rate or liquidity relevant to the Shares or the Transaction.

EXTRAORDINARY EVENTS:

Consequences of Merger Events:

Share-for-Share: Modified Calculation Agent Adjustment

Share-for-Other: Cancellation and Payment on that portion of the Other Consideration that consists of cash;

Modified Calculation Agent Adjustment on the remainder of the Other Consideration

Component Adjustment Share-for-Combined:

Tender Offer:

Applicable; <u>provided</u> that the definition of "Tender Offer" in Section 12.1 of the Equity Definitions will be amended by replacing the phrase "greater than 10% and less than 100% of the outstanding voting shares of the Issuer" in the third and fourth line thereof with "(a) greater than 15% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer is being made by any entity or person other than the Issuer or any subsidiary thereof or (b) greater than 20% and less than 100% of the outstanding Shares of the Issuer in the event that such Tender Offer

is being made by the Issuer or any subsidiary thereof".

Consequences of Tender Offers:

Modified Calculation Agent Adjustment Share-for-Share: Share-for-Other: Modified Calculation Agent Adjustment Share-for-Combined: Modified Calculation Agent Adjustment

New Shares: In the definition of New Shares in Section 12.1(i) of the Equity Definitions, the text in clause (i)

thereof shall be deleted in its entirety and replaced with "publicly quoted, traded or listed on any of the New York Stock Exchange, The NASDAQ Global Select Market or The NASDAQ Global

Market (or their respective successors)".

For purposes of the Transaction,

the definition of Merger Date in Section 12.1(c) of the Equity Definitions shall be amended to add "each of the Announcement Date and" immediately following the word "means";

- the definition of Tender Offer Date in Section 12.1(e) of the Equity Definitions shall be amended to add "each of the Announcement Date and" immediately preceding the words "the date"; and
- the definition of "Announcement Date" in Section 12.1(1) of the Equity Definitions is hereby amended by (a) replacing the words "a firm" with the word "any bona fide" in the second and fourth lines thereof, (b) replacing the word "leads to the" with the words ", if completed, would lead to a" in the third and the fifth lines thereof, (c) replacing the words "voting shares" with the word "Shares" in the fifth line thereof, (d) inserting the words "by any bona fide entity that is reasonably likely to be a party to the transaction" after the word "announcement" in the second and the fourth lines thereof, (e) inserting the words "or to explore the possibility of engaging in" after the words "engage in" in the second line thereof and (f) inserting the words "or to explore the possibility of purchasing or otherwise obtaining" after the word "obtain" in the fourth line thereof.

Composition of Combined Consideration: Not Applicable

Cancellation and Payment; provided that in addition to the provisions of Section 12.6(a)(iii) of the Nationalization, Insolvency or Delisting: Equity Definitions, it shall constitute a Delisting if the Exchange is located in the United States and the Shares are not immediately re-listed, re- traded or re-quoted on any of the New York Stock

Exchange, The NASDAQ Global Market or The NASDAQ Global Select Market (or their respective successors); if the Shares are immediately re-listed, re-traded or re-quoted on any such exchange or quotation system, such exchange or quotation system shall thereafter be deemed to be the Exchange.

Additional Disruption Events:

Change in Law:

Applicable; provided that (i) any determination as to whether (A) the adoption of or any change in any applicable law or regulation (including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute) or (B) the promulgation of or any change in the interpretation by any court, tribunal or regulatory authority with competent jurisdiction of any applicable law or regulation (including any action taken by a taxing authority), in each case, constitutes a "Change in Law" shall be made without regard to Section 739 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 or any similar legal certainty provision in any legislation enacted, or rule or regulation promulgated, on or after the Trade Date, (ii) Section 12.9(a)(ii) of the Equity Definitions is hereby amended by replacing the parenthetical beginning after the word "regulation" in the second line thereof the words "(including, for the avoidance of doubt and without limitation, (x) any tax law or (y) adoption or promulgation of new regulations authorized or mandated by existing statute)" and (iii) by, immediately following the word "Transaction" in clause (x) thereof, adding the phrase "in the manner contemplated by the Hedging Party on the Trade Date".

Failure to Deliver:

Insolvency Filing:

Hedging Disruption:

Increased Cost of Hedging:

Loss of Stock Borrow:

Maximum Stock Loan Rate:

Applicable

Applicable

Applicable

200 bps

Increased Cost of Stock Borrow: Applicable
Initial Stock Loan Rate: 25 bps

Determining Party:

For all applicable events, Dealer; *provided* that, when making any determination or calculation as "Determining Party," Dealer shall be bound by the same obligations relating to required acts of the Calculation Agent as set forth in Section 1.40 of the Equity Definitions and this Confirmation as if

Determining Party were the Calculation Agent. All calculations and determinations made by the Determining Party shall be made in good faith and in a commercially reasonable manner.

Following any determination or calculation by Determining Party hereunder, upon a written request by Issuer, Determining Party will promptly (but in any event within five Scheduled Trading Days) provide to Issuer in writing a report (in a commonly used file format for the storage and manipulation of financial data) displaying in reasonable detail the basis for such determination or calculation (including any assumptions used in the making of such determination or calculation), it being understood that in no event will Determining Party be obligated to share with Issuer any proprietary or confidential data or information or any proprietary or confidential models used by it in making such determination or calculation or any information that is subject to an obligation not to

disclose such information.

Hedging Party: For all applicable events, Dealer

Non-Reliance: Applicable

Agreements and Acknowledgements Regarding

Hedging Activities:

Applicable

Additional Acknowledgments:

3. Calculation Agent:

Applicable

Dealer; <u>provided</u> that following the occurrence of an Event of Default of the type described in Section 5(a)(vii) of the Agreement with respect to which Dealer is the sole Defaulting Party, if the Calculation Agent fails to timely make any calculation, adjustment or determination required to be made by the Calculation Agent hereunder or to perform any obligation of the Calculation Agent hereunder and such failure continues for five (5) Exchange Business Days following notice to the Calculation Agent by Issuer of such failure the Issuer shall have the right to designate a nationally recognized third-party dealer in over-the-counter corporate equity derivatives to act, during the period commencing on the date such Event of Default occurred and ending on the Early Termination Date with respect to such Event of Default, as the Calculation Agent.

All calculations and determinations by the Calculation Agent shall be made in good faith and in a commercially reasonable manner. Following any calculation made by the Calculation Agent hereunder, upon a prior written request by the Issuer, the Calculation Agent will provide to the Issuer by email to the email address provided by the Issuer in such prior written request a report (in a commonly used file format for the storage and manipulation of financial data) displaying in reasonable detail the basis for such calculation and specifying the particular section of the Confirmation pursuant to which such calculation or determination is being made (and in the event that more than one section of the Confirmation would permit the Calculation Agent to make an adjustment upon the occurrence of a specific event, then the Calculation Agent shall specify the particular section number pursuant to which the Calculation Agent is making the adjustment hereunder); provided, however, that in no event will the Calculation Agent be obligated to share with the Issuer any proprietary or confidential data or information or any proprietary models used by it.

4. Account Details and Notices:

(a) Account for delivery of Shares to Issuer:

Shares to be delivered to: Computershare 250 Royal Street Canton, MA 02021 ATTN: Client Operations (Align Technology, Inc)

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(b) Account for payments to Issuer:

Bank of America Acct: provided ABA: provided

(c) Account for payments to Dealer:

Bank: Citibank NA New York

BIC: provided

F/O: Citibank New York

A/C: provided

Ref: NY Swap Operations

Financial Institution's delivery instructions:

Citigroup Global Markets Inc DTC 0505 Name: Citibank NA A/C: provided

For purposes of this Confirmation:

(i) Address for notices or communications to Issuer:

Align Technology, Inc. 410 N. Scottsdale Road, Suite 1300 Tempe, Arizona 85281 Attn: Legal Department

(ii) Address for notices or communications to Dealer:

Citibank, N.A.
388 Greenwich Street, 8th Floor
New York, NY 10013
Attention: Equity Derivatives
Telephone No.: provided
Email: provided

5. Amendments to the Equity Definitions and Agreement.

- (a) Section 9.2(a)(iii) of the Equity Definitions is hereby amended by deleting the words "the Excess Dividend Amount, if any, and".
- (b) Section 11.2(a) of the Equity Definitions is hereby amended by deleting the words "a diluting or concentrative effect on the theoretical value of the relevant Shares" and replacing them with the words "a material economic effect on the relevant Transaction".
- (c) The first sentence of Section 11.2(c) of the Equity Definitions, prior to clause (A) thereof, is hereby amended to read as follows: '(c) If "Calculation Agent Adjustment" is specified as the Method of Adjustment in the related Confirmation of a Share Option Transaction or Share Forward Transaction, then, following the announcement or occurrence of any Potential Adjustment Event, the Calculation Agent will determine in its commercially reasonable judgment whether such Potential Adjustment Event has a material economic effect on the Transaction and, if so, will (i) make appropriate adjustment(s), if any, to any one or more of:' and the portion of such sentence immediately preceding clause (ii) thereof is hereby amended by replacing the words "diluting or concentrative" with the words "material economic".
- (d) Section 11.2(e)(vii) of the Equity Definitions is hereby amended by deleting the words "diluting or concentrative effect on the theoretical value of the relevant Shares" and replacing them with the words "any other corporate event involving the Issuer that in the commercially reasonable judgment of the Calculation Agent has a material economic effect on the relevant Transaction".
- (e) Section 12.6(c)(ii) of the Equity Definitions is hereby amended by replacing the words "the Transaction will be cancelled," in the first line with the words "Dealer will have the right to cancel the Transaction,".
- (f) Section 12.9(b)(iv) of the Equity Definitions is hereby amended by (A) deleting (1) subsection (A) in its entirety, (2) the phrase "or (B)" following subsection (A) and (3) the phrase "in each case" in subsection (B); and (B) deleting the phrase "neither the Non-Hedging Party nor the Lending Party lends Shares in the amount of the Hedging Shares or" in the penultimate sentence.
- (g) Section 12.9(b)(v) of the Equity Definitions is hereby amended by (A) adding the word "or" immediately before subsection "(B)" and deleting the comma at the end of subsection (A); and (B)(1) deleting subsection (C) in its entirety, (2) deleting the word "or" immediately preceding subsection (C) and (3) replacing in the penultimate sentence the words "either party" with "the Hedging Party" and (4) deleting clause (X) in the final sentence.
- (h) Section 2(a)(iii) of the Agreement is hereby amended by deleting the words "or Potential Event of Default" in clause (1) of such Section and deleting the word "and" immediately before subsection (3) and deleting clause "(3)" in its entirety.

6. <u>Alternative Termination Settlement</u>.

Notwithstanding anything to the contrary herein, or in the Equity Definitions, if at any time (i) an Early Termination Date occurs or (ii) the Transaction is cancelled or terminated upon the occurrence of an Extraordinary Event (other than (i) an Insolvency, a Nationalization, a Merger Event or a Tender Offer, in each case, in which the consideration or proceeds to be paid to holders of Shares consists solely of cash or (ii) an Event of Default in which Issuer is the Defaulting Party or a Termination

Event in which Issuer is an Affected Party, which Event of Default or Termination Event resulted from an event or events within Issuer's control), if either party would owe any amount to the other party pursuant to Section 6(d)(ii) of the Agreement or any Cancellation Amount pursuant to Article 12 of the Equity Definitions (any such amount, a "Payment Amount"), then such payment shall be paid as set forth under the Agreement or Equity Definitions, as the case may be, unless Issuer makes an election to the contrary no later than the Early Termination Date or the date on which such Transaction is terminated or cancelled, in which case Issuer or Dealer, as the case may be, shall deliver to the other party a number of Shares (or a number of units, each comprising the number or amount of the securities or property that a hypothetical holder of one Share would receive in the case of a Nationalization, Insolvency or Merger Event, as the case may be (each such unit, an "Alternative Delivery Unit")), with a value equal to the Payment Amount, as determined by the Calculation Agent. In determining the number of Shares (or Alternative Delivery Units) required to be delivered under this provision, the Calculation Agent may take into account a number of factors, including, without limitation, the market price of the Shares (or Alternative Delivery Units) on the Early Termination Date or the date of early cancellation or termination, as the case may be. Additionally, if such delivery is made by Dealer, the Calculation Agent shall take into account the prices at which Dealer purchases Shares (or Alternative Delivery Units) to fulfill its delivery obligations under this Section 6; provided that in determining the composition of any Alternative Delivery Unit, if the relevant Merger Event involves a choice of consideration to be received by holders, such holder shall be deemed to have elected to receive the maximum possible amount of cash. If delivery of Shares or Alternative Delivery Units, as the case may be, pursuant to this Section 6 is to be made by Issuer, paragraphs 2 through 8 of Annex A hereto shall apply as if (A) such delivery were a settlement of the Transaction to which Net Share Settlement applied, (B) the Buyer Cash Settlement Payment Date were the Early Termination Date or the date of early cancellation or termination, as the case may be, and (C) the Forward Cash Settlement Amount were equal to (x) zero minus (y) the Payment Amount owed by Issuer.

- 7. Special Provisions for Merger Transactions. Notwithstanding anything to the contrary herein or in the Equity Definitions:
 - (a) Issuer agrees that:
- (i) Issuer will use its commercially reasonable efforts such that Issuer will not during the term of the Transaction make, or, to the extent within its control, permit to be made, any public announcement (as defined in Rule 165(f) under the Securities Act of 1933, as amended (the "Securities Act")) of any Merger Transaction or potential Merger Transaction unless such public announcement is made prior to the open or after the close of the regular trading session on the Exchange for the Shares.
- (ii) To the extent that an announcement of a potential Merger Transaction occurs during the term of the Transaction and Dealer has not provided notice to Issuer as promptly as reasonably practicable following such announcement that Dealer will cause the Transaction to be cancelled or terminated in whole pursuant to "Extraordinary Events" in Section 2 above, then as soon as practicable following such announcement (but in any event prior to the next opening of the regular trading session on the Exchange), Issuer shall provide Dealer with written notice specifying (x) Issuer's average daily "Rule 10b-18 purchases" (as defined in Rule 10b-18) during the three full calendar months immediately preceding the Announcement Date that were not effected through Dealer or its affiliates and (y) the number of Shares purchased pursuant to the block purchase proviso in Rule 10b-18(b)(4) under the Exchange Act for the three full calendar months preceding the Announcement Date. Such written notice shall be deemed to be a certification by Issuer to Dealer that such information is true and correct. Issuer understands that Dealer will use this information in calculating the trading volume for purposes of Rule 10b-18. In addition, Issuer shall promptly notify Dealer of the earlier to occur of the completion of such transaction and the completion of the vote by target shareholders. Issuer acknowledges that any such public announcement may trigger the provision set forth in Section 9 below.

Accordingly, Issuer acknowledges that its actions in relation to any such announcement or transaction must comply with the standards set forth in Section 11(b) below.

(b) Upon the occurrence of any public announcement of a Merger Transaction, Dealer may in a good faith and commercially reasonable manner elect either to (i) apply the provisions of Section 9 below or (ii) treat the occurrence of such announcement as an Additional Termination Event with respect to which the Transaction shall be the sole Affected Transaction, Issuer shall be the sole Affected Party and Dealer shall be the party entitled to designate an Early Termination Date pursuant to Section 6(b) of the Agreement (a "Merger Termination Event"). In the event that the Dealer elects to treat the Merger Transaction as a Merger Termination Event under this Section 7(b), then neither the provisions of "Extraordinary Events: Consequences of Merger Events" set forth above in this Confirmation nor the provisions of Section 8 below shall apply.

"Merger Transaction" means any merger, acquisition or similar transaction involving a recapitalization of Issuer as contemplated by Rule 10b-18(a)(13)(iv) under the Exchange Act.

8. Special Provisions for Acquisition Transaction Announcements.

- (a) If an Acquisition Transaction Announcement occurs on or prior to the final Valuation Date, then the Forward Price shall be determined as if the words "minus (ii) the Discount" were deleted from the definition thereof. If an Acquisition Transaction Announcement occurs after the Trade Date but prior to the Lock-Out Date, the Lock-Out Date shall be deemed to be the date of such Acquisition Transaction Announcement.
- (b) "Acquisition Transaction Announcement" means (i) the announcement of an Acquisition Transaction, (ii) an announcement that Issuer or any of its subsidiaries has entered into an agreement, a letter of intent or an understanding designed to result in an Acquisition Transaction, (iii) the announcement of the intention to solicit or enter into, or to explore strategic alternatives or other similar undertaking that may include, an Acquisition Transaction, or (iv) any announcement subsequent to an Acquisition Transaction Announcement relating to a material amendment, a material extension, withdrawal or other material change to the subject matter of the previous Acquisition Transaction Announcement. For the avoidance of doubt, the term "announcement" as used in the definition of Acquisition Transaction Announcement refers to any public announcement whether made by Issuer or any subsidiary or agent thereof or by a bona fide third party that is reasonably likely to be a party to the Acquisition Transaction.
- (c) "Acquisition Transaction" means (i) any Merger Event (for purposes of this definition, the definition of Merger Event shall be read with the references therein to "100%" being replaced by "25%" and to "50%" by "75%" and without reference to the clause beginning immediately following the definition of Reverse Merger therein to the end of such definition), Tender Offer or Merger Transaction or any other transaction involving the merger of Issuer with or into any third party, (ii) the sale or transfer of all or substantially all of the assets or liabilities of Issuer, (iii) a recapitalization, reclassification, binding share exchange or other similar transaction or (iv) any acquisition, lease, exchange, transfer, disposition (including by way of spin-off or distribution) of assets or liabilities (including any capital stock or other ownership interests in subsidiaries) or other similar event by Issuer or any of its subsidiaries where the aggregate consideration transferable or receivable by or to Issuer or its subsidiaries exceeds 25% of the market capitalization of Issuer.

9. <u>Dealer Adjustments</u>.

In the event that Dealer determines, in a good faith and commercially reasonable manner that, based on advice of legal counsel, it is appropriate with regard to any legal, regulatory or self-regulatory requirements or related policies and procedures (whether or not such requirements, policies or procedures are imposed by law or have been voluntarily adopted by Dealer, and including, without limitation, Rule 10b-18, Rule 10b-5, Regulations 13D-G and Regulations 14 D-E under the Exchange Act; provided that such requirements, policies and procedures relate to legal and regulatory issues and are generally applicable in similar situations and applied in a consistent manner in similar transactions), for Dealer to refrain from purchasing Shares or engaging in other market activity or to purchase fewer than the number of Shares or to engage in fewer or smaller other market transactions Dealer would otherwise purchase or engage in on any Trading Day on or prior to the last day of the Potential Purchase Period, then Dealer may, in its reasonable discretion, elect that a Market Disruption Event shall be deemed to have occurred on such Trading Day. Dealer shall notify Issuer upon the exercise of Dealer's rights pursuant to this Section 9 and the Trading Days affected by it and shall subsequently notify Issuer on the day Dealer believes that the circumstances giving rise to such exercise have changed.

10. Covenants.

Issuer covenants and agrees that:

(a) Until the end of the Potential Purchase Period (as defined below), neither it nor any of its affiliated purchasers (as defined in Rule 10b-18 under the Exchange Act) shall directly or indirectly (which shall be deemed to include the writing or purchase of any cash-settled or other derivative or structured Share repurchase transaction with a hedging period, calculation period or settlement valuation period or similar period that overlaps with the Transaction) purchase, offer to purchase, place any bid or limit order relating to a purchase of or commence any tender offer relating to Shares (or any security convertible into or exchangeable for Shares) without the prior written approval of Dealer or take any other action that would cause the purchase by Dealer of any Shares in connection with this Confirmation not to qualify for the safe harbor provided in Rule 10b-18 under the Exchange Act (assuming for the purposes of this paragraph that such safe harbor were otherwise available for such purchases); provided that this Section 10(a) shall not (i) limit the Issuer's ability, pursuant to its employee incentive plan or dividend reinvestment program to re-acquire Shares in connection with the related equity transactions, (ii) limit the Issuer's ability to withhold shares to cover tax liabilities associated with such equity transactions, (iii) limit the Issuer's ability to grant stock and options to "affiliated purchasers" (as defined in Rule 10b-18) or the ability of such affiliated purchaser to acquire such stock or options, provided that in connection with any such purchase Issuer will be deemed to represent to Dealer that such purchase does not constitute a "Rule 10b-18 Purchase" (as defined in Rule 10b-18) (any such incentive or compensatory plan, program or

policy of Issuer, a "Compensatory Plan"), or (iv) limit any purchases by affiliated purchasers (as defined in Rule 10b-18) of the Issuer in an amount, in aggregate, not to exceed 5% of ADTV (as defined in Rule 10b-18) for such Exchange Business Day, which purchases shall be executed by Dealer (or its affiliate) and made pursuant to documentation and terms reasonably acceptable to Dealer and Issuer. "Potential Purchase Period" means the period from, and including, the Trade Date to, and including, the latest of (i) the last day of any Buyer Settlement Valuation Period, (ii) the earlier of (A) the date ten Exchange Business Days immediately following the last day of the Calculation Period and (B) the Scheduled Valuation Date and (iii) if an Early Termination Date occurs or the Transaction is cancelled pursuant to Article 12 of the Equity Definitions, a date determined by Dealer in its commercially reasonable discretion and communicated to Issuer no later than the Exchange Business Day immediately following such date.

- (b) Without limiting the generality of Section 13.1 of the Equity Definitions, it is not relying, and has not relied, upon Dealer or any of its representatives or advisors with respect to the legal, accounting, tax or other implications of this Agreement and that it has conducted its own analyses of the legal, accounting, tax and other implications of this Agreement, and that Dealer and its affiliates may from time to time effect transactions for their own account or the account of customers and hold positions in securities or options on securities of Issuer and that Dealer and its affiliates may continue to conduct such transactions during the term of this Agreement. Without limiting the generality of the foregoing, Issuer acknowledges that Dealer is not making any representations or warranties or taking any position or expressing any view with respect to the treatment of the Transaction under any accounting standards including ASC Topic 260, *Earnings Per Share*, ASC Topic 815, *Derivatives and Hedging*, or ASC Topic 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging Contracts in Entity's Own Equity* (or any successor issue statements) or under FASB's Liabilities & Equity Project.
- (c) Neither it nor any affiliates shall take any action that would cause a restricted period (as defined in Regulation M under the Exchange Act ("**Regulation M**")) to be applicable to any purchases of Shares, or of any security for which Shares is a reference security (as defined in Regulation M), by Issuer or any affiliated purchasers (as defined in Regulation M) of Issuer during the Potential Purchase Period.
- (d) It will not make any election or take any other action in connection with the Transaction while aware of any material nonpublic information regarding Issuer or the Shares.
- (e) It shall not declare or pay any Extraordinary Dividend until the Exchange Business Day immediately following the last day of the Potential Purchase Period.
- (f) Issuer represents and warrants that it and any of its subsidiaries has not applied, and shall not, until after the first date on which no portion of the Transaction remains outstanding following any final exercise and settlement, cancellation or early termination of the Transaction, apply, for a loan, loan guarantee, direct loan (as that term is defined in the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act")) or other investment, or to receive any financial assistance or relief under any program or facility (collectively "Financial Assistance") that (a) is established under applicable law (whether in existence as of the Trade Date or subsequently enacted, adopted or amended), including without limitation the CARES Act and the Federal Reserve Act, as amended, and (b) (i) requires under applicable law (or any regulation, guidance, interpretation or other pronouncement of a governmental authority with jurisdiction for such program or facility) as a condition of such Financial Assistance, that the Issuer comply with any requirement not to repurchase, or otherwise agree, attest, certify or warrant that it has not, as of the date specified in such condition, repurchased, or will not repurchase, any equity security of Issuer, and that Issuer has not, as of the date specified in the condition, made a capital distribution or will not make a capital distribution, or (ii) where the terms of the Transaction would cause Issuer to fail to satisfy any condition for application for or receipt or retention of the Financial Assistance (collectively "Restricted Financial Assistance"); provided, that Issuer or any of its subsidiaries may apply for Restricted Financial Assistance if Issuer either (a) determines based on the advice of outside counsel of national standing that the terms of the Transaction would not cause Issuer or any of its subsidiaries to fail to satisfy any condition for application for or receipt or retention of such Financial Assistance based on the terms of the program or facility as of the date of such advice or (b) delivers to Dealer evidence or other guidance from a governmental authority with jurisdiction for such program or facility that the Transaction is permitted under such program or facility (either by specific reference to the Transaction or by general reference to transactions with the attributes of the Transaction in all relevant respects).

11. Representations, Warranties and Acknowledgments.

- (a) Issuer hereby represents and warrants to Dealer on the date hereof and on and as of the Initial Share Delivery Date that:
- (i) (A) None of Issuer and its officers and directors is aware of any material nonpublic information regarding Issuer or the Shares, and is entering into the Transaction in good faith and not as part of a plan or scheme to evade the prohibitions of federal securities laws, including, without limitation, Rule 10b-5 under the Exchange Act and (B) Issuer agrees

not to alter or deviate from the terms of this Confirmation or enter into or alter a corresponding or hedging transaction or position with respect to the Shares (including, without limitation, with respect to any securities convertible or exchangeable into the Shares) during the term of this Confirmation. Without limiting the generality of the foregoing, all reports and other documents filed by Issuer with the Securities and Exchange Commission pursuant to the Exchange Act when considered as a whole (with the more recent such reports and documents deemed to amend inconsistent statements contained in any earlier such reports and documents) do not contain any untrue statement of a material fact or any omission of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances in which they were made, not misleading.

- (ii) The transactions contemplated by this Confirmation have been authorized under Issuer's publicly announced program to repurchase Shares.
- (iii) Issuer is not entering into this Confirmation to facilitate a distribution of the Shares (or any security convertible into or exchangeable for Shares) or in connection with a future issuance of securities.
- (iv) Issuer is not entering into this Confirmation to create actual or apparent trading activity in the Shares (or any security convertible into or exchangeable for Shares) or to manipulate the price of the Shares (or any security convertible into or exchangeable for Shares) in violation of the federal securities laws.
- (v) There have been no purchases of Shares in Rule 10b-18 purchases of blocks pursuant to the once-a-week block exception contained in Rule 10b-18(b)(4) by or for Issuer or any of its affiliated purchasers during each of the four calendar weeks preceding the Trade Date and during the calendar week in which the Trade Date occurs ("Rule 10b-18 purchase", "blocks" and "affiliated purchaser" each being used as defined in Rule 10b-18).
- (vi) Issuer is as of the date hereof and after giving effect to the transactions contemplated hereby will be, Solvent. As used in this paragraph, the term "Solvent" means, with respect to a particular date, that on such date (A) the present fair market value (or present fair saleable value) of the assets of Issuer is not less than the total amount required to pay the liabilities of Issuer on its total existing debts and liabilities (including contingent liabilities) as they become absolute and matured, (B) Issuer is able to realize upon its assets and pay its debts and other liabilities, contingent obligations and commitments as they mature and become due in the normal course of business, (C) assuming consummation of the transactions as contemplated by this Confirmation, Issuer is not incurring debts or liabilities beyond its ability to pay as such debts and liabilities mature, (D) Issuer is not engaged in any business or transaction, and does not propose to engage in any business or transaction, for which its property would constitute unreasonably small capital after giving due consideration to the prevailing practice in the industry in which Issuer is engaged, (E) Issuer is not a defendant in any civil action that could reasonably be expected to result in a judgment that Issuer is or would become unable to satisfy, (F) Issuer is not "insolvent" (as such term is defined under Section 101(32) of the U.S. Bankruptcy Code (Title 11 of the United States Code) (the "Bankruptcy Code")) and (G) Issuer would be able to purchase Shares with an aggregate purchase price equal to the Prepayment Amount in compliance with the corporate laws of the jurisdiction of its incorporation.
- (vii) Issuer is not, and after giving effect to the transactions contemplated hereby will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.
- (viii) No state or local (including non-U.S. jurisdictions) law, rule, regulation or regulatory order applicable to the Shares would give rise to any reporting, consent, registration or other requirement (including without limitation a requirement to obtain prior approval from any person or entity) as a result of Dealer or its affiliates owning or holding (however defined) Shares other than any such law, rule, regulation or regulatory order that applies (A) to the beneficial ownership of Shares under the Exchange Act or (B) solely as a result of the business, identity, place of business or jurisdiction of organization of Dealer or any such affiliate.
- (b) Issuer acknowledges and agrees that the Initial Shares may be sold short to Issuer. Issuer further acknowledges and agrees that Dealer may purchase Shares in connection with the Transaction, which Shares may be used to cover all or a portion of such short sale or may be delivered to Issuer. Such purchases and any other market activity by Dealer will be conducted independently of Issuer by Dealer as principal for its own account. All of the actions to be taken by Dealer in connection with the Transaction shall be taken by Dealer independently and without any advance or subsequent consultation with Issuer. It is the intent of the parties that the Transaction comply with the requirements of Rule 10b5-1(c)(1)(i)(B) of the Exchange Act, and the parties agree that this Confirmation shall be interpreted to comply with the requirements of such Rule, and Issuer shall not take any action that results in the Transaction not so complying with such requirements. Without limiting the generality of the preceding sentence, Issuer acknowledges and agrees that (A) Issuer does not have, and shall not attempt to exercise, any influence over how, when or whether Dealer effects any market transactions in connection with the Transaction and (B) neither Issuer nor its officers or employees shall, directly or indirectly, communicate any information regarding Issuer

or the Shares to any employee of Dealer or its Affiliates that have been identified by Dealer to Issuer in writing as employees responsible for executing market transactions in connection with the Transaction. Issuer also acknowledges and agrees that any amendment, modification, waiver or termination of this Confirmation must be effected in accordance with the requirements for the amendment or termination of a "plan" as defined in Rule 10b5-1(c) under the Exchange Act. Without limiting the generality of the foregoing, any such amendment, modification, waiver or termination shall be made in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act, and no such amendment, modification or waiver shall be made at any time at which Issuer or any officer or director of Issuer is aware of any material nonpublic information regarding Issuer or the Shares.

- (c) Each of Issuer and Dealer represents and warrants to the other that it is an "eligible contract participant" as defined in Section 1a(12) of the U.S. Commodity Exchange Act, as amended.
- (d) Each of Issuer and Dealer acknowledges that the offer and sale of the Transaction to it is intended to be exempt from registration under the Securities Act by virtue of Section 4(2) thereof. Accordingly, it represents and warrants to the other party that (i) it has the financial ability to bear the economic risk of its investment in the Transaction and is able to bear a total loss of its investment, (ii) it is an "accredited investor" as that term is defined in Regulation D as promulgated under the Securities Act, (iii) it is entering into the Transaction for its own account and without a view to the distribution or resale thereof and (iv) the assignment, transfer or other disposition of the Transaction has not been and will not be registered under the Securities Act and is restricted under this Confirmation, the Securities Act and state securities laws.
 - (e) In addition to the representations, warranties and covenants in the Agreement, Dealer represents warrants and covenants to Issuer that:
 - (i) In addition to the covenants in the Agreement and herein, Dealer agrees to use commercially reasonable efforts, during the Calculation Period and any Buyer Settlement Valuation Period for the Transaction, to make all purchases of Shares in connection with such Transaction in a manner that would comply with the limitations set forth in clauses (b)(1), (b)(2), (b)(3) and (b)(4) and (c) of Rule 10b-18, as if such rule were applicable to such purchases and taking into account any applicable Securities and Exchange Commission no-action letters as appropriate, and subject to any delays between the execution and reporting of a trade of the Shares on the Exchange and other circumstances beyond Dealer's control; *provided* that, during the Calculation Period, the foregoing agreement shall not apply to purchases made to dynamically hedge for Dealer's own account or the account of its affiliate(s) the optionality arising under the Transaction (including, for the avoidance of doubt, timing optionality); *provided further* that, without limiting the generality of this Section, Dealer shall not be responsible for any failure to comply with Rule 10b-18(b)(3) to the extent any transaction that was executed (or deemed to be executed) by or on behalf of Issuer or an "affiliated purchaser" (as defined under Rule 10b-18) pursuant to a separate agreement is not deemed to be an "independent bid" or an "independent transaction" for purposes of Rule 10b-18(b)(3).
 - (ii) Dealer hereby represents and covenants to Issuer that it has implemented policies and procedures, taking into consideration the nature of its business, reasonably designed to ensure that (A) individuals making investment decisions related to the Transaction do not have access to material nonpublic information regarding Issuer or the Shares and (B) individuals of Dealer that are in possession of material nonpublic information regarding the Issuer or the Shares have not, while in possession of such material nonpublic information, participated in any offsetting transaction(s) in respect of such Transaction.
 - (iii) Within one Exchange Business Day of purchasing any Shares on behalf of Issuer pursuant to the once-a-week block exception set forth in paragraph (b)(4) of Rule 10b-18, Dealer shall notify Issuer of the total number of Shares so purchased.
 - (iv) On the first Exchange Business Day of each week, Dealer shall provide weekly reports (the "Weekly Reports") in connection with the Transaction to the Issuer and to such other persons or agents of the Issuer as the Issuer shall reasonably designate in writing, by electronic mail to the Issuer or its designee. Each Weekly Report shall include the ADTV (as defined in Rule 10b-18) in the Shares for each Scheduled Trading Day during the immediately preceding week (as defined and determined in accordance with Rule 10b-18, as defined herein), the 10b-18 VWAP for each such Scheduled Trading Day and the high and low price on each such Scheduled Trading Day. For the avoidance of doubt and notwithstanding anything to the contrary in the two immediately preceding sentences, the 10b-18 VWAP for purposes of this Master Confirmation shall be determined pursuant the language opposite the caption "10b-18 VWAP" in Section 1 of this Confirmation and not on the basis of, or by reference to, the 10b-18 VWAP set forth in any Weekly Report.

12. Acknowledgements of Issuer.

- (a) Issuer agrees, understands and acknowledges that:
- (i) during the period from (and including) the Trade Date to (and including) the Settlement Date, Dealer and its Affiliates may buy or sell Shares or other securities or buy or sell options or futures contracts or enter into swaps or other derivative transactions in order to adjust its Hedge Position with respect to the Transaction;
- (ii) Dealer and its Affiliates also may be active in the market for the Shares or options, futures contracts, swaps or other derivative transactions relating to the Shares other than in connection with hedging activities in relation to the Transaction;
- (iii) Dealer shall make its own determination as to whether, when and in what manner any hedging or market activities in Issuer's securities or other securities or transactions shall be conducted and shall do so in a manner that it deems appropriate to hedge its price and market risk with respect to the Transaction; and
- (iv) any such market activities of Dealer and its Affiliates may affect the market price and volatility of the Shares, including the 10b-18 VWAP and the Forward Price, each in a manner that may be adverse to Issuer.

(b) Issuer:

- (i) is an "institutional account" as defined in FINRA Rule 4512(c);
- (ii) is capable of evaluating investment risks independently, both in general and with regard to all transactions and investment strategies involving a security or securities, and will exercise independent judgment in evaluating the recommendations of Dealer or its associated persons, unless it has otherwise notified Dealer in writing; and
 - (iii) will notify Dealer if any of the statements contained in clause (i) or (ii) of this Section 12(b) ceases to be true.

13. Delivery of Cash.

For the avoidance of doubt, other than payment of the Prepayment Amount by Issuer, nothing in this Confirmation shall be interpreted as requiring Issuer to cash settle the Transaction hereunder, except in circumstances where cash settlement is within Issuer's control or in those circumstances in which holders of the Shares would also receive cash.

14. Other Provisions.

- (a) Issuer agrees and acknowledges that Dealer is a "financial institution" and "financial participant" within the meaning of Sections 101(22) and 101(22A) of the Bankruptcy Code. The parties hereto further agree and acknowledge that it is the intent of the parties that (A) this Confirmation is a "securities contract," as such term is defined in Section 741(7) of the Bankruptcy Code, with respect to which each payment and delivery hereunder or in connection herewith is a "termination value," "payment amount" or "other transfer obligation" within the meaning of Section 362 of the Bankruptcy Code and a "settlement payment," within the meaning of Section 546 of the Bankruptcy Code, and (B) Dealer is entitled to the protections afforded by, among other sections, Sections 362(b)(6), 362(b)(17), 362(o), 546(e), 555 and 561 of the Bankruptcy Code.
- (b) Dealer and Issuer hereby agree and acknowledge that Dealer has authorized Issuer to disclose the Transaction to any and all persons, and there are no express or implied agreements, arrangements or understandings to the contrary, and authorizes Issuer to use any information that Issuer receives or has received with respect to the Transaction in any manner.
- (c) In the event Issuer becomes the subject of proceedings ("Bankruptcy Proceedings") under the Bankruptcy Code or any other applicable bankruptcy or insolvency statute, any rights or claims of Dealer hereunder in respect of the Transaction shall rank for all purposes no higher than, but on a parity with, the rights or claims of holders of Shares, and Dealer hereby agrees that its rights and claims hereunder shall be subordinated to those of all parties with claims or rights against Issuer (other than common stockholders) to the extent necessary to assure such ranking. Without limiting the generality of the foregoing, after the commencement of Bankruptcy Proceedings, the claims of Dealer hereunder shall for all purposes have rights equivalent to the rights of a holder of a percentage of the Shares equal to the aggregate amount of such claims (the "Claim Amount") taken as a percentage of the sum of (i) the Claim Amount and (ii) the aggregate fair market value of all outstanding Shares on the record date for distributions made to the holders of such Shares in the related Bankruptcy Proceedings. Notwithstanding any right it might otherwise have to assert a higher priority claim in any such Bankruptcy

Proceedings, Dealer shall be entitled to receive a distribution solely to the extent and only in the form that a holder of such percentage of the Shares would be entitled to receive in such Bankruptcy Proceedings, and, from and after the commencement of such Bankruptcy Proceedings, Dealer expressly waives (i) any other rights or distributions to which it might otherwise be entitled in such Bankruptcy Proceedings in respect of its rights and claims hereunder and (ii) any rights of setoff it might otherwise be entitled to assert in respect of such rights and claims.

- (d) Notwithstanding any provision of this Confirmation or any other agreement between the parties to the contrary, neither the obligations of Issuer nor the obligations of Dealer hereunder are secured by any collateral, security interest, pledge or lien.
- (e) Each party waives any and all rights it may have to set off obligations arising under the Agreement and the Transaction against other obligations between the parties, whether arising under any other agreement, applicable law or otherwise.
- (f) Notwithstanding anything to the contrary herein, Dealer may, by prior notice to Issuer, satisfy its obligation to deliver any Shares or other securities on any date due (an "**Original Delivery Date**") by making separate deliveries of Shares or such securities, as the case may be, at more than one time on or prior to such Original Delivery Date, so long as the aggregate number of Shares and other securities so delivered on or prior to such Original Delivery Date is equal to the number required to be delivered on such Original Delivery Date.
- (g) It shall constitute an Additional Termination Event with respect to which the Transaction is the sole Affected Transaction and Issuer is the sole Affected Party and Dealer shall be the party entitled to designate an Early Termination Date pursuant to Section 6(b) of the Agreement if, at any time on or prior to the Valuation Date, the price per Share on the Exchange, as determined by the Calculation Agent, is at or below the Threshold Price (as specified in Schedule I).
- (h) Notwithstanding any other provision in this Confirmation to the contrary requiring or allowing Dealer to purchase, sell, receive or deliver any Shares or other securities to or from Issuer, Dealer may designate any of its affiliates (a "Designated Affiliate") to purchase, sell, receive or deliver such Shares or other securities and otherwise to perform Dealer's obligations in respect of the Transaction and any such designee may assume such obligations. Dealer shall be discharged of its obligations to Issuer to the extent that such Designated Affiliate performs in full all of the obligations of Dealer designated by Dealer to such Designated Affiliate under this Transaction.

15. Transfer and Assignment.

Dealer may transfer or assign its rights and obligations hereunder and under the Agreement ("**Transfer**"), in whole or in part, to any of its Affiliates that have a credit rating that is not lower than the credit rating of Dealer immediately prior to the proposed time of such Transfer (or whose obligations are guaranteed by an entity of equivalent credit quality) without the consent of Issuer. Dealer will provide prompt written notice of any such transfer to Issuer.

16. US Resolution Stay.

- (a) Recognition of the U.S. Special Resolution Regimes.
- (i) In the event that Dealer becomes subject to a proceeding under (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder or (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder (a "U.S. Special Resolution Regime") the transfer from Dealer of this Confirmation, and any interest and obligation in or under, and any property securing, this Confirmation, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Confirmation, and any interest and obligation in or under, and any property securing, this Confirmation were governed by the laws of the United States or a state of the United States.
- (ii) In the event that Dealer or an Affiliate becomes subject to a proceeding under a U.S. Special Resolution Regime, any Default Rights (as defined in 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable ("**Default Right**")) under this Confirmation that may be exercised against Dealer are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Confirmation were governed by the laws of the United States or a state of the United States.

- (b) Limitation on Exercise of Certain Default Rights Related to an Affiliate's Entry Into Insolvency Proceedings. Notwithstanding anything to the contrary in this Confirmation, the parties expressly acknowledge and agree that:
- (i) Issuer shall not be permitted to exercise any Default Right with respect to this Confirmation or any Affiliate Credit Enhancement that is related, directly or indirectly, to an Affiliate of Dealer becoming subject to receivership, insolvency, liquidation, resolution, or similar proceeding (an "Insolvency Proceeding"), except to the extent that the exercise of such Default Right would be permitted under the provisions of 12 C.F.R. 252.84, 12 C.F.R. 47.5 or 12 C.F.R. 382.4, as applicable; and
- (ii) Nothing in this Confirmation shall prohibit the transfer of any Affiliate Credit Enhancement, any interest or obligation in or under such Affiliate Credit Enhancement, or any property securing such Affiliate Credit Enhancement, to a transferee upon or following an Affiliate of Dealer becoming subject to an Insolvency Proceeding, unless the transfer would result in the Issuer being the beneficiary of such Affiliate Credit Enhancement in violation of any law applicable to the Issuer.
 - (iii) For the purpose of this paragraph:
 - (A) "Affiliate" is defined in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).
 - (B) "Credit Enhancement" means any credit enhancement or credit support arrangement in support of the obligations of Dealer under or with respect to this Confirmation, including any guarantee, collateral arrangement (including any pledge, charge, mortgage or other security interest in collateral or title transfer arrangement), trust or similar arrangement, letter of credit, transfer of margin or any similar arrangement.
- (c) U.S. Protocol. If Issuer has previously adhered to, or subsequently adheres to, the ISDA 2018 U.S. Resolution Stay Protocol as published by the International Swaps and Derivatives Association, Inc. as of July 31, 2018 (the "ISDA U.S. Protocol"), the terms of the ISDA U.S. Protocol shall be incorporated into and form a part of this Confirmation and the terms of the ISDA U.S. Protocol shall supersede and replace the terms of this section. For purposes of incorporating the ISDA U.S. Protocol, Dealer shall be deemed to be a Regulated Entity, Issuer shall be deemed to be an Adhering Party, and this Confirmation shall be deemed to be a Protocol Covered Agreement. Capitalized terms used but not defined in this paragraph shall have the meanings given to them in the ISDA U.S. Protocol.
- (d) Pre-existing In-Scope Agreements. Dealer and Issuer agree that to the extent there are any outstanding "in-scope QFCs," as defined in 12 C.F.R. § 252.82(d), that are not excluded under 12 C.F.R. § 252.88, between Dealer and Issuer that do not otherwise comply with the requirements of 12 C.F.R. § 252.2, 252.81–8 (each such agreement, a "**Preexisting In-Scope Agreement**"), then each such Preexisting In-Scope Agreement is hereby amended to include the foregoing provisions in this section, with references to "this Confirmation" being understood to be references to the applicable Preexisting In-Scope Agreement.

17. Governing Law; Jurisdiction; Waiver.

THIS CONFIRMATION AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS CONFIRMATION SHALL BE GOVERNED BY THE LAWS OF THE STATE OF NEW YORK. THE PARTIES HERETO IRREVOCABLY SUBMIT TO THE EXCLUSIVE JURISDICTION OF THE COURTS OF THE STATE OF NEW YORK AND THE UNITED STATES COURT FOR THE SOUTHERN DISTRICT OF NEW YORK IN CONNECTION WITH ALL MATTERS RELATING HERETO AND WAIVE ANY OBJECTION TO THE LAYING OF VENUE IN, AND ANY CLAIM OF INCONVENIENT FORUM WITH RESPECT TO, THESE COURTS.

EACH PARTY HEREBY IRREVOCABLY WAIVES (ON ITS OWN BEHALF AND, TO THE EXTENT PERMITTED BY APPLICABLE LAW, ON BEHALF OF ITS STOCKHOLDERS) ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THE TRANSACTION OR THE ACTIONS OF THE OTHER PARTY OR THE OTHER PARTY'S AFFILIATES IN THE NEGOTIATION, PERFORMANCE OR ENFORCEMENT HEREOF.

Remainder of Page Intentionally Blank

Please confirm that the foregoing correctly sets forth the terms of our agreement by executing this Confirmation and returning an original or electronic copy in accordance with the notice provisions set forth in Section 4.

Confirmed as of the date first written above:

ALIGN TECHNOLOGY, INC

By: /s/ John Morici

Name: John Morici

Title: CFO and SVP, Global Finance

CITIBANK, N.A.

By: /s/ Eric Natelson

Name: Eric Natelson Title: Authorized Signatory

BUYER SETTLEMENT PROVISIONS

1. The following Buyer Settlement Provisions shall apply to the Transaction to the extent indicated under the Confirmation:

Settlement Currency: USD

Settlement Method Election: Applicable; provided that (i) Section 7.1 of the Equity Definitions is hereby amended by deleting the word "<u>Physical</u>" in the sixth line thereof and replacing it with the words "<u>Net Share</u>" and (ii) the Electing Party may make a settlement method election only if the Electing Party represents and warrants to Dealer in writing on the date it notifies Dealer of its election that, as of such date, the Electing Party is not aware of any material nonpublic information concerning Issuer or the Shares and is electing the settlement method in good faith and not as part of a plan or scheme to evade compliance with the federal securities laws.

Electing Party: Buyer

Settlement Method

Election Date: In respect of any Valuation Date, the earlier of (i) the Scheduled Valuation Date and (ii) the third Exchange Business

Day immediately following the Valuation Date designated in an Acceleration (if any) (in which case the election under Section 7.1 of the Equity Definitions shall be made no later than 10 minutes prior to the open of trading on the Exchange on such second Exchange Business Day), as the case may be.

Default Settlement Method: Cash Settlement

Forward Cash Settlement

Amount: The Settlement Amount multiplied by the Buyer Settlement Price.

Buyer Settlement Price: The average of the 10b-18 VWAPs for the Observation Dates that are Trading Days in the Buyer Settlement

Valuation Period, subject to the provisions opposite the caption "Market Disruption Event" in the Confirmation, plus USD 0.05 (in each case, plus interest on such amount during the Buyer Settlement Valuation Period at the rate of interest for Issuer's long term, unsecured and unsubordinated indebtedness, as determined in good faith and in a commercially reasonable manner by the Calculation Agent).

Buyer Settlement

Valuation Period: A number of Scheduled Trading Days selected by Dealer in its commercially reasonable discretion, beginning on the

Scheduled Trading Day immediately following the earlier of (i) the Scheduled Valuation Date or (ii) the

Exchange Business Day immediately following the Valuation Date.

Cash Settlement: If Cash Settlement is applicable, then Buyer shall pay to Seller the absolute value of the Forward Cash Settlement

Amount on the Buyer Cash Settlement Payment Date.

Buyer Cash Settlement

Payment Date: The date one Settlement Cycle following the last day of the Buyer Settlement Valuation Period.

Net Share Settlement

Procedures: If Net Share Settlement is applicable, Net Share Settlement shall be made in accordance with paragraphs 2 through 8

below.

- 2. Net Share Settlement shall be made by delivery on the Buyer Cash Settlement Payment Date of a number of Shares satisfying the conditions set forth in paragraph 3 below (the "Registered Settlement Shares"), or a number of Shares not satisfying such conditions (the "Unregistered Settlement Shares"), in either case with a value equal to the absolute value of the Forward Cash Settlement Amount, with such Shares' value based on the value thereof to Dealer (which value shall, in the case of Unregistered Settlement Shares, take into account a commercially reasonable illiquidity discount), in each case, as determined by the Calculation Agent in good faith and in a commercially reasonable manner.
 - 3. Buyer may deliver Registered Settlement Shares pursuant to paragraph 2 above only if:
- (a) a registration statement covering public resale of the Registered Settlement Shares by Dealer (the "Registration Statement") shall have been filed with the Securities and Exchange Commission under the Securities Act and been declared or otherwise become effective on or prior to the date of delivery, and no stop order shall be in effect with respect to the Registration Statement; and a printed prospectus relating to the Registered Settlement Shares (including any prospectus supplement thereto, the "Prospectus") shall have been delivered to Dealer, in such quantities as Dealer shall reasonably have requested, on or prior to the date of delivery;
- (b) the form and content of the Registration Statement and the Prospectus (including, without limitation, any sections describing the plan of distribution) shall be reasonably satisfactory to Dealer;
- (c) as of or prior to the date of delivery, Dealer and its agents shall have been afforded a reasonable opportunity to conduct a due diligence investigation with respect to Buyer customary in scope for underwritten offerings of equity securities for companies of a similar size and in a similar industry and the results of such investigation are satisfactory to Dealer, in its discretion; and
- (d) as of the date of delivery, an agreement (the "**Underwriting Agreement**") shall have been entered into with Dealer in connection with the public resale of the Registered Settlement Shares by Dealer substantially similar to underwriting agreements customary for underwritten offerings of equity securities for companies of a similar size and in a similar industry, in form and substance commercially reasonably satisfactory to Dealer, which Underwriting Agreement shall include, without limitation, provisions substantially similar to those contained in such underwriting agreements relating, without limitation, to the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates and the provision of customary opinions, accountants' comfort letters and lawyers' negative assurance letters.
 - 4. If Buyer delivers Unregistered Settlement Shares pursuant to paragraph 2 above:
- (a) all Unregistered Settlement Shares shall be delivered to Dealer (or any affiliate of Dealer designated by Dealer) pursuant to the exemption from the registration requirements of the Securities Act provided by Section 4(a)(2) thereof;
- (b) as of or prior to the date of delivery, Dealer and any potential purchaser of any such shares from Dealer (or any affiliate of Dealer designated by Dealer) identified by Dealer shall be afforded a commercially reasonable opportunity to conduct a due diligence investigation with respect to Buyer customary in scope for private placements of equity securities for companies of a similar size and in a similar industry (including, without limitation, the right to have made available to them for inspection all financial and other records, pertinent corporate documents and other information reasonably requested by them subject to customary confidentiality agreements);
- (c) as of the date of delivery, Buyer shall enter into an agreement (a "**Private Placement Agreement**") with Dealer (or any affiliate of Dealer designated by Dealer) in connection with the private placement of such shares by Buyer to Dealer (or any such affiliate) and the private resale of such shares by Dealer (or any such affiliate), substantially similar to private placement purchase agreements customary for private placements of equity securities for companies of a similar size and in a similar industry, in form and substance commercially reasonably satisfactory to Dealer, which Private Placement Agreement shall include, without limitation, provisions substantially similar to those contained in such private placement purchase agreements for companies of a similar size and in a similar industry relating, without limitation, to the indemnification of, and contribution in connection with the liability of, Dealer and its affiliates and the provision of customary opinions, accountants' comfort letters and lawyers' negative assurance letters, and shall provide for the payment by Buyer of all reasonable fees and expenses in connection with such resale, including all reasonable fees and expenses of counsel for Dealer, and shall contain representations, warranties, covenants and agreements of Buyer reasonably necessary or advisable to establish and maintain the availability of an exemption from the registration requirements of the Securities Act for such resales; and

- (d) in connection with the private placement of such shares by Buyer to Dealer (or any such affiliate) and the private resale of such shares by Dealer (or any such affiliate), Buyer shall, if so requested by Dealer, prepare, in cooperation with Dealer, a private placement memorandum in form and substance reasonably satisfactory to Dealer.
- 5. Dealer, itself or through an affiliate (the "Selling Agent") or any underwriter(s), will sell all, or such lesser portion as may be required hereunder, of the Registered Settlement Shares or Unregistered Settlement Shares and any Makewhole Shares (as defined below) (together, the "Settlement Shares") delivered by Buyer to Dealer pursuant to paragraph 6 below commencing on the Buyer Cash Settlement Payment Date and continuing until the date on which the aggregate Net Proceeds (as such term is defined below) of such sales, as determined by Dealer, is equal to the absolute value of the Forward Cash Settlement Amount (such date, the "Final Resale Date"). If the proceeds of any sale(s) made by Dealer, the Selling Agent or any underwriter(s), net of any fees and commissions (including, without limitation, underwriting or placement fees) customary for similar transactions under the circumstances at the time of the offering, together with carrying charges and expenses incurred in connection with the offer and sale of the Shares (including, but without limitation to, the covering of any over-allotment or short position (syndicate or otherwise)) (the "Net Proceeds") exceed the absolute value of the Forward Cash Settlement Amount, Dealer will refund, in USD, such excess to Buyer on the date that is two (2) Currency Business Days following the Final Resale Date, and, if any portion of the Settlement Shares remains unsold, Dealer shall return to Buyer on that date such unsold Shares.
- 6. If the Calculation Agent determines that the Net Proceeds received from the sale of the Registered Settlement Shares or Unregistered Settlement Shares or any Makewhole Shares, if any, pursuant to this paragraph 6 are less than the absolute value of the Forward Cash Settlement Amount (the amount in USD by which the Net Proceeds are less than the absolute value of the Forward Cash Settlement Amount being the "Shortfall" and the date on which such determination is made, the "Deficiency Determination Date"), Buyer shall, on the Exchange Business Day next succeeding the Deficiency Determination Date (the "Makewhole Notice Date"), deliver to Dealer, through the Selling Agent, a notice of Buyer's election that Buyer shall either (i) pay an amount in cash equal to the Shortfall on the day that is one (1) Currency Business Day after the Makewhole Notice Date, or (ii) deliver additional Shares. If Buyer elects to deliver to Dealer additional Shares, then Buyer shall deliver additional Shares in compliance with the terms and conditions of paragraph 3 or paragraph 4 above, as the case may be (the "Makewhole Shares"), on the first Clearance System Business Day that is also an Exchange Business Day following the Makewhole Notice Date in such number as the Calculation Agent reasonably believes would have a market value on that Exchange Business Day equal to the Shortfall. Such Makewhole Shares shall be sold by Dealer in accordance with the provisions above; provided that if the sum of the Net Proceeds from the sale of the originally delivered Shares and the Net Proceeds from the sale of any Makewhole Shares is less than the absolute value of the Forward Cash Settlement Amount then Buyer shall, at its election, either make such cash payment or deliver to Dealer further Makewhole Shares until such Shortfall has been reduced to zero.
- 7. Notwithstanding the foregoing, in no event shall the aggregate number of Settlement Shares for the Transaction be greater than the Share Cap (as specified in Schedule I). Buyer represents and warrants (which shall be deemed to be repeated on each day that the Transaction is outstanding) that the Share Cap is equal to or less than the number of Shares determined according to the following formula:

A - B

Where A = the number of authorized but unissued shares of Buyer that are not reserved for future issuance on the date hereof; and

B = the maximum number of Shares required to be delivered to third parties if Buyer elected Net Share Settlement of all transactions in the Shares (other than the Transaction) with all third parties that are then currently outstanding and unexercised.

Subsidiaries of Align Technology, Inc.

The registrant's principal subsidiary as of December 31, 2021, are as follows:

Entity

Align Technology Switzerland GmbH, Switzerland

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-258449, No. 333-214493, No. 333-190351, No. 333-143319, No. 333-134477, No. 333-125586, No. 333-161054, No. 333-176134, No. 333-168548, No. 333-116912) of Align Technology, Inc. of our report dated February 25, 2022 relating to the financial statements and financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California February 25, 2022

CERTIFICATION

I, Joseph M. Hogan, certify that:

- 1. I have reviewed this annual report on Form 10-K of Align Technology, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2022

/s/ JOSEPH M. HOGAN

Joseph M. Hogan President and Chief Executive Officer

CERTIFICATION

I, John F. Morici, certify that:

- 1. I have reviewed this annual report on Form 10-K of Align Technology, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2022

/s/ JOHN F. MORICI

John F. Morici

Chief Financial Officer and Executive Vice President, Global Finance

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Align Technology, Inc. (the "Company") on Form 10-K for the period ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the

- Sarbanes-Oxley Act of 2002, that: (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

		By:	/S/ JOSEPH M. HOGAN
Date:	February 25, 2022	Name:	Joseph M. Hogan
	•	Title:	President and Chief Executive Officer
Securities	1 0	, , , , , , , , , , , , , , , , , , , ,	Form 10-K for the period ending December 31, 2021 as filed with the pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the
(1) The R	eport fully complies with the require	ements of section 13(a) or 15(d) of the S	ecurities Exchange Act of 1934; and
(2) The ir	nformation contained in the Report f	airly presents, in all material respects, th	e financial condition and result of operations of the Company.
		Ву:	/s/ JOHN F. MORICI
Date:	February 25, 2022	Name:	John F. Morici

Chief Financial Officer and Executive Vice President, Global Finance

Title: